SOUTH CAROLINA

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

PUBLIC HEALTH LABORATORY

SERVICES GUIDE

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LABORATORY DIRECTOR

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DHEC PUBLIC HEALTH LABORATORY
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PURPOSE OF MANUAL

The purpose of this manual is to provide our clients with information about the laboratory testing availability and to provide a guide for collecting and submitting specimens.

This edition can also be accessed on SC DHEC website at:

http://www.scdhec.gov/Health/FHPF/LabCertificationServices/LabServicesGuide/

MISSION STATEMENT

The mission of the Public Health Laboratory (PHL) is to provide specialized laboratory testing for accurate screening, diagnosis, prevention and surveillance of disease, foodborne illness, and congenital disorders to improve public health and the quality of life for the South Carolina community.

GENERAL INFORMATION

The Public Health Laboratory, S.C. Department of Health and Environmental Control, formerly named the Bureau of Laboratories, is a multi-disciplinary, integrated source of diagnostic services including analytical support and consultation for physicians, private laboratories, hospitals, and county health departments. The Public Health Laboratory is prepared to assist in any national public health emergency.

PHYSICAL ADDRESS:

The Public Laboratory is located in the James A. Hayne Building at 8231 Parklane Road, Columbia, South Carolina 29223, on the campus of the State Park Health Center. State Park is located between Highway 555 (Farrow Road), Parklane Road and the I-77 connector (Bull Street extension or S.C. I-277) two miles north of I-20; 2 miles west of Columbia Mall. Using the Parklane Road Entrance, the Hayne Building is at the end of the first left turn.

HOURS OF BUSINESS

The official working hours are from 8:00 A.M. to 4:00 P.M. Monday through Friday.

AFTER HOURS, WEEKEND AND HOLIDAY

The laboratory maintains an ON-CALL Roster for all weekends and holidays. Individuals requesting information or services of an emergency nature can call the main number, 803-896-0800. This number transfers to an answering service who will contact the Director on call.

EMERGENCY RESPONSE/ DISASTER PREPAREDNESS

As part of the DHEC's Emergency Preparedness Plan of Action for emergencies, the Public Health Laboratory is equipped and the staff is trained to respond rapidly and effectively to a medical emergency natural disaster or Act of Bioterrorism. If the emergency occurs outside of regular working hours, personnel will be called back or work overtime as needed to provide laboratory support.

SPECIMEN RECEIVING

Specimens transported by DHEC's courier service are placed in specially marked boxes and are picked up by lab staff from the Columbia Mills building between 5:00 AM and 6:00 AM Tuesday through Friday. Specimens are picked up by laboratory staff on Saturday and DHEC observed nonfederal holidays between 7:00 AM and 8:00 AM from the U.S. Post Office and DHEC at 301 Gervais Street. These are sorted and stored according to established protocol to be accessioned on the next working day.

Specimens sent by first class mail are delivered from the Columbia Mills building by DHEC's courier service at 9:00 AM Monday through Friday. Those with a Parklane Road address are picked up by the Supply staff at 9:00 AM. The U.S. Post Office delivers at approximately 12:30 PM, Monday through Friday.

Specimens are accepted at the Hayne Building during business hours of 8:00 AM to 4:00 PM Monday through Friday, except for state holidays. Private couriers delivering specimens at the back entrance of the Hayne Building should call Specimen Management Section at 803-896-0898 for pick up. Private individuals delivering specimens must enter the building through the front entrance. The American Security Officer will assist them.

AFTER HOURS DELIVERY OF SPECIMENS

Specimens other than Newborn Screening samples will not be accepted after hours unless special arrangements have been made with the laboratory section conducting the test. This person will notify the American Security Officer on duty that a delivery is expected.

The after hours depository located in the rear of the Hayne Building is for animal heads being delivered for rabies testing only. Please do not put specimens and cultures in the depository.

Newborn screening specimens can be accepted at the Security Desk of the Hayne Building after business hours. Couriers delivering from hospitals will sign the specimens in on a log kept at the Security Desk. Holiday and Saturday delivery of Newborn screening specimens shipped using FedEx/UPS can also be accepted by the Security Desk.

CONTACT PERSONS AND PHONE NUMBERS

(Area Code 803)

Results.....896-0800
Laboratory Request Forms/Mailing Containers.....896-0913
Facilities Maintenance (Laboratory Instrument Services).....896-0919
Laboratory Director…….Robert B. Dixon, Ph.D. HCLD… 896-0965
Assistant Laboratory Director…….....Horng-Yuan Kan, PhD.....……896-9725
Director, Chemistry Division……Ona O. Adair, Ph.D. 896-0991
Director, Microbiology Division…… Megan L. Davis, M.S. 896-0870
Support Division Manager.....Melissa Dawson, M.S.....896-2331
Director, Logistic Division…… David C Rivers…. 896-0923
Office of Quality Assurance ……..Patricia A. Myers, B.S.,MT (ASCP)……896-3897
Office of Laboratory Safety……...Andrea M. Causey, M.S..... 896-0956
Laboratory Information Management Systems (LIMS) Administrator…..Linda Conway……..896-4777

LABORATORY ACCREDITATION AND CERTIFICATION

CLINICAL TESTING - CLIA ID # 42D0658606

TESTING POLICIES

PERSONS AUTHORIZED TO ORDER TESTS

The Laboratory will accept clinical laboratory specimens for testing from physicians, health departments, and hospital laboratories, or as provided by South Carolina statues. These senders will be responsible for receiving, relating, interpreting, and/or distributing the data. A clinical laboratory specimen is described as any material derived from the human body for the purpose of diagnosis, prevention, treatment or assessment for medical or legal purposes. Inanimate substances and other samples submitted for examination (e.g., food samples, animal heads for rabies, veterinary specimens, etc) may be accepted from private citizens at the discretion of the Division Director, Laboratory Supervisor, or Laboratory Director.

VERIFICATION OF ORALLY ORDERED TESTS

When additional tests are requested by telephone, the caller is asked to follow up with a written request on letterhead, or an additional laboratory request form for the test(s) requested. Please send written request to the attention of the Specimen Management Section or to the Laboratory Supervisor. The additional test(s) will not be performed until the written request is received. With time sensitive tests, the specimen may be tested immediately and the results held until the written request is received. In this case the caller may fax the request to the Laboratory. The caller should obtain the proper fax number at the time of their request. To process and test a specimen without a written request, the oral request is recorded in the telephone log of the area receiving the call: **Exception: No HIV tests will be performed without written request at the time of testing**. All blood specimens will be discarded if a written request is not received within seven working days.

REQUESTING REPEAT TESTING ON A SEROLOGY SPECIMEN

To request a repeat serology test call Specimen Management Section at (803) 896-0898. Specimens are discarded after seven working days. A retest request must be made within that time period. Repeat testing on the same specimen may not always be feasible. The testing laboratory may request additional information to determine the best approach. In some cases, a second (new) specimen for testing may be recommended. In other cases, the patient's clinical history may provide an explanation for the initial result, and retesting may not be necessary.

SPECIMENS REFERRED FOR TESTING TO CDC

Laboratories wishing to send specimens directly to CDC should contact the Microbiology Division at (803) 896-0870. The sender will be assigned a State Health Department number and will be asked to fax or mail to the Laboratory a copy of the information being sent. CDC forms are also available from the Laboratory.

OTHER REFERENCE LABORATORIES

If a specimen is sent to a reference laboratory for initial, follow-up or verification testing by the Public Health Laboratory, the sender will be notified that the specimen has been referred. The original result report from the reference laboratory is forwarded or faxed to the sender. A copy of the report is maintained by the laboratory.

STAT TESTING

Requests received in the morning mail will be put in the day's run. The results will be telephoned to the requestor, followed by a hard copy report or electronic accessible report. If the request is for a test that will not be performed immediately, the requestor will be informed by telephone when the test will be performed and the result available.

CONFIRMATORY TESTING

When confirmatory tests are necessary, patient results are not released until all testing is completed.

LABORATORY SPECIMENS SENT TO THE PUBLIC HEALTH LABORATORY IN ERROR

Specimens sent to the laboratory in error will be returned to the sender as soon as possible.

CORRECTION OF PATIENT INFORMATION

All requested changes to the request form by the sender must be documented on letterhead, dated and signed by the requestor. A returned copy of the original laboratory report requesting the missing information is acceptable to communicate changes needed as long as the sender states clearly what is needed, dates, and signs or photocopy the report**.** The patient's record will be updated to reflect the change and a corrected report will be mailed to the sender.

SPECIMEN REJECTION & DISCLAIMER CRITERIA

"Exceeds 24 Hours Limit for Valid Testing"

The following tests have a 24 hour specimen limit for valid testing and CANNOT be collected and/or sent any Friday or 24 hours BEFORE a state holiday: Hepatitis C, Quantitation by PCR (RNA), HIV-1 PCR Quantitative (RNA), CBC, CD4 and/or Malaria specimen sent as an EDTA tube with no thick and/or thin smear.

The following disclaimers are considered universal rejections as they apply to all specimens submitted for testing. Specific test related rejections are listed in the Alpha Listing of Test (Section II) and the Collection Procedures (Section III).

NO SPECIMEN RECEIVED

When a request form is received without a specimen, a computer inquiry is made to determine if the specimen has been received with another test request. If so, the specimen is obtained and aliquoted for all tests. If no specimen is found, the request form is numbered, processed, and reported "No specimen received."

NO REQUEST FORM RECEIVED

If a specimen is received without a request form and the sender cannot be identified from the specimen label, the specimen will be held awaiting telephone inquiry or delayed receipt of form. After seven days, the blood specimen is discarded. Gen-Probe Aptima swab specimen is discarded after 60 days and the Gen-Probe Aptima urine specimen is discarded after 30 days.

NO NAME ON SPECIMEN

When a specimen is received without an identifying number or patient name, it WILL NOT be tested. An exception may be made for a specimen that cannot be recollected because of its unique anatomic source, collection method or time of collection. Examples include: CSF, peritoneal pleural and synovial fluids, autopsy, biopsy, or organ specimens, and specimens collected prior to the initiation of antimicrobial therapy.

NO NAME ON REQUEST FORM

When a request form is received without a name, and there is no other identification on the form that matches the information on the specimen, a call is placed to the submitter requesting a corrected copy. An exception will be reported as "No name on form" if corrected copy NOT received by completion of specimen processing.

NO TEST REQUESTED

When a specimen is received, and there is no test marked on the request form and the sender is known, the specimen will be reported as "No test marked. If you would like this specimen tested, write the test number on this form and send to the lab. We will discard the specimen, 7 days after the date received shown above." Note: Only the blood specimen is discarded after 7 days. When the corrected request form is received, the specimen will be tested. Note: If the specimen received has a 24 hour limit for valid testing; the sender will be notified by phone to fax a corrected request form.

OTHER MISSING INFORMATION

If other necessary information is missing, the specimen will be tested and the missing information will be requested by phone, fax, or mail. The result will be held until the missing information is received.

MISMATCHED INFORMATION

When the name on the request form and the specimen do not match, the specimen will not be tested. It will be reported as, "Name on specimen differs from name on request form."

PARTIAL INFORMATION MATCHES

When there is a partial name match and other data on the request form matches, it is most probably the same patient. The name on the tube is written on the request form, and the test is run and a disclaimer added to the report.

SPECIMEN BROKEN OR LEAKED IN TRANSIT

When a broken or leaking specimen is received, every attempt will be made to salvage it without compromising the integrity of the specimen.

INCORRECT SPECIMEN RECEIVED

If the specimen received is incorrect for the test requested, a search is initiated to determine if the correct specimen was received with a request form for a different test. If the specimen is found, testing will be done. If the specimen is not found, the specimen is reported as, "incorrect specimen submitted."

UNSATISFACTORY SPECIMENS

Specimens collected for tests that have a 24 hour specimen limit for valid testing CANNOT be collected and/or sent any Friday or 24 hours BEFORE a state holiday: Hepatitis C, Quantitation by PCR (RNA), HIV-1 PCR Quantitative (RNA), CBC, CD4 and/or Malaria specimen sent as an EDTA tube with no thick and/or thin smear.

The Public Health Laboratory will not examine and will discard specimens which are received in unsatisfactory condition. The reasons for the rejection will be reported to the sender on the standard laboratory report form. Unsatisfactory conditions include but are not limited to:

Hemolyzed, chylous, or contaminated specimen,
Specimen received beyond the acceptable time for testing,
Specimen collected too soon or too late during the disease-state for the test requested,
Specimen was stored and shipped at improper temperature,
Specimen is nonviable, or decomposed,
Specimen quantity insufficient

Specimens that have some degree of hemolysis, icteric, or chylous, will be tested if the degree of hemolysis or lipemia does not interfere with the examination. The undesirable condition will be indicated on the report form.

RESULTS REPORTING POLICIES

All laboratory reports generated are considered confidential information. The reports will be released only to authorized persons. **Sample Master Result Point:** Reports can be accessed via the internet this allows instant and real access to results. Reports are mailed daily to clients without access to the internet. Clients can only view information on orders that have been logged in with their customer ID. **Newborn Screening Results** are mailed daily. Contact the laboratory at 803-896-4777 for more information.

TELEPHONE RESULTS

Panic or Critical Values or Life-Threatening results and/or public health emergencies are telephoned to the appropriate person. A result will not be left on voice mail or an answering machine. A message to call the Public Health Laboratory for a report will be left.

COPIES OF TEST REPORTS

Newborn Screening: One copy is sent to the hospital submitting the specimen and one to the physician whose name has been entered on the request form as the healthcare provider. If no attending physician is listed, a single copy is sent to the hospital or submitter. **All other tests**: Reports can be accessed via the internet, and one copy is mailed to the name entered in the sender section of the request form. We regret that we cannot honor requests for multiple copies. If multiple copies of other test reports are needed, we suggest you photocopy the original report issued.

REMAILING OF RESULTS REPORTS

If a physician or clinic to which the patient has been referred requests a copy of a test result, the report will be reprinted with the original sender number and mailed as requested. If the report is not received, please call 803-896-0800 or 803-896-4777.

CORRECTING REPORTING ERRORS

If an error or the possibility of an error is discovered by the laboratory after results have been mailed or accessed via result point, the sender will be notified immediately by telephone. The error will be explained and the correct result given. A corrected hard-copy report will be issued with the comment "Corrected Report".

If an error in reporting is discovered by the sender, the laboratory should be notified immediately. The error will be corrected and a corrected report will be mailed. The corrected report will be printed with the comment "Corrected Report".

DISEASE REPORTING

The Code of Laws of South Carolina (1976) Section 44-29-10: Regulation 61-20 mandates that the Commissioner of DHEC is to publish annually a list of diseases to be reported by physicians and laboratories. This list can be found on the Internet at https://scdhec.gov/sites/default/files/Library/CR-009025.pdf.

All communicable disease outbreaks and unusual disease occurrences should be reported so that appropriate control measures can be implemented.

SECTION II

ALPHA LISTING OF TEST INFORMATION

ACANTHAMOEBA CONVENTIONAL PCR & REAL-TIME PCR

Synonyms: Free-living ameba

Test Laboratory: Referred to the CDC Division of Parasitic Diseases and Malaria

Days Test Performed: Forwarded upon request.

Request Form: CDC Specimen Referral Form 50.34 Rev. 9-2002. Requesting laboratories must have a state public health laboratory number to include on this form. Please call 803-896-0805 to obtain a number.

Special Instructions: This test is no longer performed at the SC DHEC Public Health Laboratory. The test requires CDC approval prior to submission. For additional instructions regarding specimen selection, storage, shipping and test methodology, contact the Clinical Microbiology Laboratory – 803-896-0805.

Specimen &Volume: 1 ml CSF or small piece of tissue (brain, lung, corneal scrapings

Container: Sterile screw-capped tube containing small amount of Page's amoeba saline

Storage/Shipping Temperature: Store and ship overnight at room temperature

Shipping Description: Specimen should be shipped overnight to the CDC by the submitting facility.

Rejection Criteria, specific: Specimen refrigerated or frozen, For universal rejections, See **Section I**

Methodology: PCR

Add. Information: NA

CPT Code: 87181

ACID FAST BACILLI CULTURE (AFB) - See "Mycobacterial Culture"

ADENOVIRUS CULTURE - See "Respiratory Virus Culture"

AEROBE REFERRED FOR IDENTIFICATION - See "Bacterial Isolate for Identification"

AIDS TESTING - See "HIV -1/HIV-2 Serology"

BACILLUS ANTHRACIS

Synonyms: Anthrax

Test Laboratory: Special Pathogens, 803-896-0777

Days Test Performed: As needed

Request Form: 1335, Test #520 or 521; Suspect agent "Bacillus anthracis"

Special Instructions: This organism has been designated as a Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777, 803-767-8118, or 803-896-0773.

BACILLUS ANTHRACIS (Continued)

Specimen & Volume: Clinical samples, clinical isolates, and environmental samples (submitted by FBI)

Container: See Special Instructions Above

Storage/Shipping Temperature: See Special Instructions Above

Shipping Description: See Special Instructions Above

Rejection Criteria, specific: See Special Instructions Above

Methodology: A variety of sentinel and LRN methods are used to confirm or rule-out bacterial isolates.

Add. Information: NA

CPT Code: NA

BACTERIAL ISOLATE, REFERRED FOR IDENTIFICATION

Synonyms: Aerobe for identification; culture for identification; *Salmonella; Shigella; Shiga-toxin Producing E. coli(STEC); Campylobacter; Neisseria; Haemophilus; Listeria; Streptococcus; ` Staphylococcus; Vibrio*; etc

Test Laboratory: Clinical Microbiology, 803-896-0805

Days Test Performed: Monday – Friday

Request Form: 1335, Test #511

Special Instructions: Consultation required for non-enteric gram negative bacilli, and gram positive cocci and gram positive bacilli that are not reportable organisms or select agents.

Specimen & Volume: Pure aerobic bacterial isolate on an agar slant. Plates may be appropriate in some circumstances. Please consult with the laboratory prior to sending isolates on plated media.

Container: Screw-cap tube containing agar slant that will support growth of isolate

Storage/Shipping Temperature: Store and ship at room temperature.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Culture nonviable; culture mixed. For universal rejections, **See Section 1**

Methodology: Conventional bio-chemicals, Vitek MS

Add. Information: NA

CPT Code: 87077

BLOOD LEAD -See "Lead, Blood"

BORDETELLA sp. Detection by PCR

Synonyms: *B. pertussis* PCR, Pertussis PCR, "whooping cough"

Test Laboratory: Virology & Rabies, 803-896-0819

Days Test Performed: Monday-Friday

Request Form: DHEC 1335, Test #115

Special Instructions: All submissions require prior approval from the Virology Section Supervisor (803-896-0820) or the Microbiology Division Director (803-896-0870).

Specimen & Volume: Only nasopharyngeal swabs will be accepted for testing. Specimens should be collected within four weeks of symptom onset and prior to antibiotic therapy. Swabs should be thin, flexible, nasopharyngeal swabs with polyester, rayon, or nylon tips and aluminum or plastic shafts.

BORDETELLA sp. Detection by PCR (Continued)

Do not use cotton, wood, or calcium alginate swabs. A pair of swabs, one for each nare, is considered one sample. Place the swabs in viral transport media
proof, screw-capped tube. Use transport media. See **Collection Procedure for *Bordetella pertussis* Detection by PCR and Culture, Section III**

Container: Viral transport media

Storage/Shipping Temperature: Ship with cold packs. Store in a refrigerator if shipping is delayed. Specimens must be received in the Virology Section within 72 hours of collection

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimens on swabs with cotton tips, calcium alginate tips or wooden shafts; Specimens shipped on transport media; Specimens received >72 hours after collection; Specimens collected >4 weeks from symptom onset; Specimens collected >5 days after the initiation of antibiotic therapy; For universal rejections, See **Section I**

Methodology: Multiplex Real-time PCR

Add. Information: This test is used to detect and differentiate between, *B. pertussis* and *B. parapertussis*

CPT Code: 87798

BOTULISM

Prompt diagnosis and early treatment of botulism are essential to minimize the otherwise great risk of death. State Health Departments and the Center for Disease Control and Prevention (CDC) offer 24-hour diagnostic consultation, epidemic investigation assistance, and laboratory services. Trivalent (ABE) Botulinal Antitoxin is available from the CDC. In order to receive these services, it is necessary to do the following:

1. Contact the DHEC/Bureau of Epidemiology, Disease Control and Surveillance consultant at **(803) 898-0861** (M-F during business hours) or digital pager **(803) 690-3756** (after hours).

2. If appropriate, call the CDC Emergency 24 hour number (**770-488-7100**) to make arrangements for immediate shipment of the antitoxin, when indicated, and for proper shipment of selected clinical specimens and/or food samples for testing.

3. Contact the DHEC Division of Microbiology (**803-896-0870**) or the Special Pathogens Laboratory (803-896-0777) to obtain faxed copy of CDC request form and South Carolina State Laboratory number. Consultation with DHEC Acute Disease Epidemiology is required prior to sending the specimen (803-898-0861 or 888-847-0902 after hours). The CDC also requires State level epidemiology consult prior to testing.

4. Specimens should be shipped directly to the CDC for testing, and should be accompanied by the CDC Specimen Referral Form 50.34.

BRUCELLA

Synonyms: Brucellosis

Test Laboratory: Special Pathogens, 803-896-0777

Days Test Performed: As needed

Request Form: 1335, Test #520 or 521; Suspect agent "Brucella"

BRUCELLA (Continued)

Special Instructions: This organism has been designated as a Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777, 803-767-8118, or 803-896-0773.

Specimen & Volume: Clinical samples, clinical isolates, and environmental samples (submitted by FBI)

Container: See Special Instructions Above

Storage/Shipping Temperature: See Special Instructions Above

Shipping Description: See Special Instructions Above

Rejection Criteria, specific: See Special Instructions Above

Methodology: A variety of sentinel and LRN methods are used to confirm or rule-out bacterial isolates.

Add. Information: NA

CPT Code: NA

BRUCELLA MICROAGGLUTINATION TEST (BMAT)

Synonyms: BMAT, Brucellosis

Test Laboratory: Special Pathogens, 803-896-0777

Days Test Performed: As needed

Request Form: 1335, Test #521, Write in "BMAT"; Suspect agent "Brucella"

Special Instructions: This organism has been designated as a Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777, 803-896-8118, or 803-896-0773. Specimen must be pre-approved by Special Pathogens department prior to testing.

Specimen & Volume: Serum approximately 1mL

Shipping Description: Call Special Pathogens lab for further instructions

Rejection Criteria, specific: Call Special Pathogens lab for further instructions

Methodology: LRN procedure for Brucella Microagglutination Test

Container: SST

Storage/Shipping Temperature: Store and ship at 2-8°C

Add. Information: NA

CPT Code: NA

BURKHOLDERIA MALLEI

Synonyms: Glanders

Test Laboratory: Special Pathogens, 803-896-0777

Days Test Performed: As needed

Request Form: 1335, Test #520 or 521; Suspect agent "Burkholderia mallei"

Special Instructions: This organism has been designated as a Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777, 803-767-8118, or 803-896-0773.

Specimen & Volume: Clinical samples, clinical isolates, and environmental samples (submitted by FBI)

BURKHOLDERIA MALLEI (Continued)

Container: See Special Instructions Above

Storage/Shipping Temperature: See Special Instructions Above

Shipping Description: See Special Instructions Above

Rejection Criteria, specific: See Special Instructions Above

Methodology: A variety of sentinel and LRN methods are used to confirm or rule-out bacterial isolates.

Add. Information: NA

CPT Code: NA

BURKHOLDERIA PSEUDOMALLEI

Synonyms: Melioidosis

Test Laboratory: Special Pathogens, 803-896-0777

Days Test Performed: As needed

Request Form: 1335, Test #520 or 521; Suspect agent "Burkholderia pseudomallei"

Special Instructions: This organism has been designated as a Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777, 803-767-8118, or 803-896-0773.

Specimen & Volume: Clinical samples, clinical isolates, and environmental samples (submitted by FBI)

Container: See Special Instructions Above

Storage/Shipping Temperature: See Special Instructions Above

Shipping Description: See Special Instructions Above

Rejection Criteria, specific: See Special Instructions Above

Methodology: A variety of sentinel and LRN methods are used to confirm or rule-out bacterial isolates.

Add. Information: NA

CPT Code: NA

CAMPYLOBACTER

Required to submit isolate or PCR+ Cary Blair if unable to obtain Campylobacter isolate.

Synonyms: NA

Test Laboratory: Clinical Microbiology, 803-896-0805

Days Test Performed: Monday – Friday.

Request Form: DHEC 1335, Test #511

Special Instructions: Important Campylobacter isolate is shipped Cold. Important Campylobacter from Cary Blair is kept cold, from collection thru shipment. Cary Blair should be shipped to arrive within 3 days from collection. Recovery goes down drastically after 3 days.

Container: Cold Shipper with Cold Packs

Specimen and Volume: Camplybacter isolates must be subbed to one of the following: A slant (Chocolate, HIA, etc) grown up in microaerophilic conditions. They should be shipped in a cold shipper with cold packs in ambient air. DO NOT send plates. A culturette can be used, simply use the swab to obtain growth from a pure isolate. Place in cold shipper with cold packs in ambient air. Campylobacter obtained by PCR methods, where laboratory unable to isolate and grow out Campylobacter, must send the original Cary Blair shipped cold.

CAMPYLOBACTER (Continued)

Required to submit isolate or PCR+ Cary Blair if unable to obtain Campylobacter isolate.

Storage/Shipping Temperature: Store stool preserved in Cary-Blair in refrigerator

Shipping Description: Cary Blair samples COLD, use cold packs in cold shippers to be received in the lab within 72 hours of collection. Isolates on slants and culturettes, Ship using cold packs in cold shippers. May use state courier for overnight delivery.

Rejection Criteria, specific: Quantity insufficient, specimen too old, improper transport media or conditions. For universal rejections, See **Section I**

Methodology: Conventional culture methods. Abbreviated biochemical analysis. VITEK MS.

Additional Information: SC 2017 List of Reportable Conditions

CPT Code: Identification 87046

CAMPYLOBACTER STOOL CULTURE

Campylobacter testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology.

Synonyms: NA

Test Laboratory: Clinical Microbiology, 803-896-0805

Days Test Performed: Monday – Friday.

Request Form: DHEC 1335, Test #508 for identification from stool. Test #511 for speciation.

Special Instructions: NA

Container: Screw-capped tube containing Cary Blair transport medium.

Specimen and Volume: Walnut sized portion of feces or 5-10 ml of liquid stool. Infant specimens may be collected in a disposable diaper with outside facing in.

Storage/Shipping Temperature: Store stool preserved in Cary-Blair media in refrigerator. Ship stool preserved in Cary-Blair transport media with cold packs to be received at the lab within 48 hours of collection. Ship raw stool on cold packs for arrival at the laboratory within 2-6 hours.

Shipping Description: See **Packing and Shipping Instructions Section IV.** May use state courier for overnight delivery.

Rejection Criteria, specific: Quantity insufficient, specimen too old, improper transport media or conditions. For universal rejections, See **Section I**

Methodology: Conventional culture methods. Abbreviated biochemical analysis. Vitek MS

Additional Information: NA

CPT Code: Identification 87046

CANDIDA AURIS

Synonyms: C. auris

Test Laboratory: Clinical Microbiology, 803-896-0805

Days Test Performed: Monday – Friday

Request Form: DHEC 1335, Test# 511 for Organism for ID

Special Instructions: NA

Container: Screw-capped tube containing agar slant that will support growth of isolate.

Storage/Shipping Temperature: Store and ship at room temperature.

Shipping Description: See **Packing and Shipping Instructions, Section IV.** May use DHEC contracted courier service for overnight delivery.

Rejection Criteria, specific: Culture non-viable; culture mixed. For universal

CANDIDA AURIS (Continued)

rejections, See **Section I**

Methodology: Bruker MS, testing performed at ARLN Regional Laboratory – Maryland State Laboratory

Add. Information: Please send the following isolates:

1. All confirmed or suspected *C. auris* from any body site (invasive or non-invasive, sterile or non-sterile). Particular attention paid to what platform is being used for identification and what it most commonly misidentifies *C. auris* as. Certain platforms are known to commonly misidentify *C. auris* as *C. haemulonii* or *C. duobushaemulonii*. The most common species for each identification method may be found here: https://www.cdc.gov/fungal/candida-auris/recommendations.html
2. Candida species other than *C. albicans* for any specimen source, but especially from invasive body sites.
3. Yeast from any specimen that are unable to be identified after identification was attempted.

CPT Code: 85025

CBC

Synonyms: Complete Blood Count with Differential

Test Laboratory: Clinical, Hematology Unit – 803-896-0890

Days Test Performed: Monday – Friday

Request Form: DHEC 1332, Test# 760

Special Instructions: Specimen must be less than 24 hours old when tested by laboratory.

Specimen Volume: 3 ml EDTA anticoagulated whole blood (dependent upon whether cells are badly distorted by excess anticoagulant) Mix well by gentle inversion.

Container: Lavender top (EDTA) vacuum tube. See **Venipuncture Procedure, Section III**, if needed.

Storage/Shipping Temperature: Store and ship at room temperature. **Do not refrigerate.**

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimens more than 24 hours old upon arrival, specimen clotted, and specimen received cold or frozen. For universal rejections, See **Section I**

Methodology: Automated Cell Counter

Add. Information: NA

CPT Code: 85025

CD4 - See "Lymphocyte Subset"

CHAGAS DISEASE - See "Parasite Serology"

CHIKUNGUNYA IgM Capture ELISA

Synonyms: CHIK IgM Serology

Test Laboratory: Virology/ Rabies, 803-896-0819

Days Test Performed: Weekly

Request Form: DHEC 1332, Test #118

Special Instructions: Paired specimens are NOT required. See **Venipuncture Procedure, Section III**

Specimen & Volume: 5 ml blood or 2 ml serum preferred; 0.5 ml serum minimum

Container: Red top vacuum tube, Serum Separator

Shipping Description: See Packing and Shipping Instructions, Section IV

CHIKUNGUNYA IgM Capture ELISA (Continued)

Storage/Shipping Temperature: Store and ship at 2-8°C

Rejection Criteria, specific: None. For universal rejections, See **Section I**

Methodology: IgM Capture ELISA

Add. Information: Positive results will be referred to CDC for additional testing.

CPT Codes: 86790

CHIKUNGUNYA VIRUS DETECTION BY REAL-TIME RT-PCR

Synonyms: Chik, Chikungunya

Test Laboratory: Virology & Rabies, 803-896-0819

Days Test Performed: Wednesdays

Request Form: DHEC 1335, Request "Trioplex RT-PCR"

Special Instructions: Paired specimens are NOT required. See **Venipuncture Procedure, Section III**; Urine collection: sterile screw-capped cup.

Specimen & Volume: 1-2 mL serum and 1-2 mL urine. Serum is required for testing.

Container: Serum Separator; Sterile, Screw-capped Cup (Urine)

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Storage/Shipping Temperature: Store and ship at 2-8°C. Freeze and ship frozen if specimen will be greater than 72 hours old when received.

Rejection Criteria, specific: None. For universal rejections, See **Section I**

Methodology: Trioplex Real-Time reverse transcriptase PCR (real-time RT-PCR)

Add. Information: Used to detect the presence of Chikungunya nucleic acid (RNA). Results are reported as negative or positive.

CPT Code: 87798

CHLAMYDIA (CT) DETECTION BY NUCLEIC ACID AMPLIFICATION

Synonyms: Gen-Probe, *C. trachomatis* Amplified Nucleic Acid Probe, Chlamydia rRNA, CT Aptima

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday-Friday

Request Form: DHEC 1332, Test #506 – CT only, Test #507 – GC and GC.

Special Instructions: Only use Gen-Probe Aptima specimen collection kit (unisex swab, vaginal swab, or urine). Patients under the age of twelve should be tested by culture.

Specimen & Volume: Swab specimen: Endocervical, validated rectal and pharyngeal swab, and/or male urethral Gen-Probe blue-shafted swab in Gen-Probe Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens (Blue Label). Vaginal specimens: Use the Gen-Probe Aptima Vaginal Swab Specimen Collection kit (Orange label) for collecting vaginal samples. Vaginal samples collected in the Aptima Unisex Swab Collection kit will be disclaimed as not FDA approved for this type of specimen. Urine specimen: Patient should not have voided within one hour of collection. Collect first 20-30 ml of the first-catch urine stream into collection cup. Transfer 2 ml of urine into Aptima Urine Specimen Transport tube so that the urine level falls within the two lines on the transport tube labeled: "fill area". (Yellow Label). See **GC/Chlamydia Gen-Probe Collection Procedure, Section III**

CHLAMYDIA (CT) DETECTION BY NUCLEIC ACID AMPLIFICATION
(Continued)

Container: Gen-Probe Aptima Unisex Swab Specimen Transport kit for endocervical and male urethral swabs; Gen-Probe Aptima Urine Specimen Transport kit for urines; Gen-Probe Aptima Vaginal Swab Specimen Collection kit for vaginal swabs

Storage/Shipping Temperature: Store and ship at room temperature. Swab specimens must be tested within 60 days of collection. Urine specimens within 30 days of collection.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimen with no swab in transport media; white swab in transport media; two swabs in transport media; urine above or below designated black lines on transport tube labeled fill area; swab specimen more than 60 days old, or urine specimen more than 30 days old. For universal rejections, See **Section I**

Methodology: Target amplification Nucleic acid Probe

Add. Information: This test is not appropriate in cases of sexual assault or abuse; patients under the age of twelve should be tested by culture

CPT Code: CT 87491; GC/CT 87491, 87591

CLINICAL CHEMISTRY

Synonyms: Serum Chemistries, TB Panel

Test Laboratory: Clinical, Chemistry Unit, 803-896-0890

Days Test Performed: Monday-Friday

Request Form: DHEC 1332, Test #715 (TB Panel)

Special Instructions: Chemistry specimens must be less than 4 days old when received for testing. If there will be a delay in mailing the specimen, freeze the serum and send to the lab the next business day on ice/cold packs. Make sure to note on the requisition that the specimen was frozen prior to shipment.

Specimen & Volume: 2-5 ml serum See **Venipuncture Procedure, Section III,** if needed.

Container: Vacutainer tube or SST

Storage/Shipping Temperature: Store refrigerated; ship on cold pack.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: None. For universal rejections, See **Section I**

Methodology: Automated Chemistry analyzer

Add. Information: NA

CPT Code: Must use individual analyte codes.

TB Panel	CPT CODE
TB Panel CPT CODE: Use individual analyte codes.	
AST (SGOT)	84450
ALT (SGPT)	84460
Total Bilirubin	82247
Phosphatase, Alkaline	84075
Uric Acid	84550
BUN	84520
Creatinine	82565
Glucose	82947
BUN/Creatinine Ratio*	NA
*Calculated Values have no CPT codes and cannot be billed	

CLOSTRIDIUM BOTULINUM – See "Botulism"

COMPLETE BLOOD COUNT- See "CBC"

CONGENITAL ADRENAL HYPERPLASIA - See "Newborn Screening"

CORYNEBACTERIUM DIPHTHERIAE, CULTURE & ID

Notify Clinical Microbiology lab prior to submission. Specimens must be received within 24 hours of collection.

Synonyms: *C. diphtheriae*

Test Laboratory: Clinical Microbiology, 803-896-0805

Days Test Performed: Monday-Friday

Request Form: DHEC 1335, Test #510 (clinical material or swab) or Test #511 (referred isolate)

Special Instructions: Notify Clinical Microbiology lab prior to submission. Specimens must be received within 24 hours of collection.

Specimen & Volume: Throat swab, NP swab, skin; referred isolate; clinical material submitted on Loeffler's slant

Container: Submit swab in transport tube (culturette), submit referred isolate on agar slant in screw capped tube. See **Bacterial Culture Collection, Section III**

Storage/Shipping Temperature: Store and ship at room temperature.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimen must be received within 24 hours of collection unless submitted on Loeffler's medium. Transport swab not used or ampule in transport swab not crushed. For universal rejections, See **Section I**

Methodology: Conventional culture methods

Add. Information: Detection of *Corynebacterium diphtheriae*

CPT Code: Culture 87070; Identification 87077

COXSACKIE VIRUS A & B CULTURE - See "Enterovirus Culture"

CRE, CRPA, CRAB

Synonyms: CRE = Carbapenem-resistant Enterbacteriaceae infections from all specimen types for the following species: E. Coli, Enterbacter, and Klebsiella. – Ship ALL. DO NOT send duplicates. Only one isolate per patient, regardless of source.
Note: also interested in testing other Enterobacteriacea that are possible CRE to include *Proteus, Providencia, Serratia or Morganella*. (With the exceptions of *Serratia* which are resistant to carbapenems and sensitive to a 3rd generation cephalosporin and *Enterobacter* spp. which are sensitive to Cefepime. These both represent a different mechanism of resistance than a carbapenemase). Ertapenem non-susceptibility is the most sensitive indicator or carbapenemase production.
CRPA = Carbapenem-resistant *Pseudomonas aeruginosa* - Ship 1st one isolated EACH Month, DO NOT send duplicates. Only one isolate per patient, regardless of source.
CRAB = Carbapenem-resistant *Acinetobacter baumannii* complex-send in all pan resistant *Acinetobacter* spp.

Test Laboratory: Clinical Microbiology 803-896-0805

Days Test Performed: Monday – Friday.

Request Form: DHEC 1335, Test #511

CRE, CRPA, CRAB (Continued)

Special Instructions: Only submit one isolate, per organism, per patient. No duplicates. **Always include a copy of the sensitivity report for each isolate sent.**

Container: Ship slants in a traditional shipper at room temperature.

Specimen and Volume: CRE – Ship ALL CRE isolates your laboratory obtains, sending in ONLY the first isolates from each patient. (no duplicates; a pure, low passage isolate is preferred submitted on a noninhibitory, non-selective agar slant). CRPA – Ship only first isolate your laboratory obtains each month.

Storage/Shipping Temperature: Store and Ship at room temperature

Shipping Description: May use state courier for overnight delivery.

Rejection Criteria, specific: Quantity insufficient, specimen too old, improper transport media or conditions. For universal rejections, See **Section I**

Methodology: mCIM, Conventional ID, VITEK MS, KBS, MBD, PCR

Additional Information: SC 2017 List of Reportable Conditions

CPT Code: Identification 87046

CRYPTOSPORIDIUM ANTIGEN

Cryptosporidium antigen testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology.

Synonyms: NA

Test Laboratory: Clinical Microbiology, 803-896-0805

Days Test Performed: Monday - Friday

Request Form: DHEC 1335, Test #406

Special Instructions: None

Specimen & Volume: Walnut sized portion fresh stool or 3 ml of liquid stool, 10% formalin preserved stool, Clary-Blair, C&S, or concentrated stool sediment

Container: Leakproof tube or container

Storage/Shipping Temperature: Store and ship on ice packs.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimen preserved in PVA; improper labeling. For universal rejections, See **Section I**

Methodology: Rapid immunoassay for the qualitative detection of *Cryptosporidium parvum* antigen

Add. Information: To detect the presence of *Cryptosporidium* oocysts

CPT Code: 87272

CYCLOSPORA

Cyclospora testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology.

Synonyms: *C. cayetanensis*

Test Laboratory: Virology, 803-896-0820

Days Test Performed: Monday - Friday

Request Form: DHEC 1335, Test #410

Special Instructions: Write Cyclospora on Other (specify) line

Specimen & Volume: Walnut sized portion of fresh stool, 3 ml liquid stool, formalin preserved stool, concentrated stool sediment

CYCLOSPORA (Continued)

Container: Transport tube in Enteric Kit with Cary-Blair medium
Storage/Shipping Temperature: Ship on cold packs
Shipping Description: See **Packing and Shipping Instructions, Section IV**
Rejection Criteria, specific: Specimen preserved in PVA. For universal rejections, See **Section I**
Methodology: FilmArray GI panel (PCR)
Add. Information: To detect the presence of cyclospora
CPT Code: 87507

CYSTICERCOSIS - See "Parasite Serology"

CYTOLOGY, PAPS SMEAR - See "PAP Test, Liquid-Based Monolayer"

DENGUE IgM

Synonyms: Dengue IgM Serology
Test Laboratory: Virology/ Rabies, 803-896-0819
Days Test Performed: Weekly
Request Form: DHEC 1332, Test #119
Special Instructions: Paired specimens are NOT required. See Venipuncture Procedure, Section III
Specimen & Volume: 5 ml blood or 2 ml serum preferred, 0.5 ml serum minimum
Container: Red top vacuum tube, Serum Separator
Storage/Shipping Temperature: Store and ship at 2-8°C
Shipping Description: See Packing and Shipping Instructions, Section IV
Rejection Criteria, specific: None. For universal rejections, See Section I
Methodology: IgM Capture ELISA
Add. Information: Positive results will be referred to CDC for additional testing.
CPT Codes: 86790

DENGUE VIRUS DETECTION BY REAL-TIME RT-PCR

Synonyms: Dengue
Test Laboratory: Virology & Rabies, 803-896-0819
Days Test Performed: As needed
Request Form: DHEC 1335, Request "Trioplex RT-PCR"
Special Instructions: Paired specimens are NOT required. See **Venipuncture Procedure, Section III**; Urine collection: sterile screw-capped cup.
Specimen & Volume: 1-2 mL serum and 1-2 mL urine. Serum is required for testing.
Container: Serum Separator; Sterile, Screw-capped Cup (Urine)
Shipping Description: See **Packing and Shipping Instructions, Section IV**
Storage/Shipping Temperature: Store and ship at 2-8°C
Rejection Criteria, specific: None. For universal rejections, See **Section I**
Methodology: Trioplex Real-Time reverse transcriptase PCR (real-time RT-PCR)
Add. Information: Used to detect the presence of Dengue nucleic acid (RNA). Results are reported as negative or positive.

DENGUE VIRUS DETECTION BY REAL-TIME RT-PCR (Continued)

CPT Code: 87798

DIPHTHERIA - See "*Corynebacterium diphtheriae"*

EBOLA VIRUS REAL-TIME RT-PCR ASSAY (EBOLA)

Synonyms: Ebola

Test Laboratory: Special Pathogens, 803-896-0777/803-896-0773

Days Test Performed: As needed

Request Form: DHEC 1335, Test #521; Suspect agent "Ebola"

Special Instructions: This organism has been designated as a Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777, 803-896-8118, or 803-896-0773. Specimen must be pre-approved by Special Pathogens department prior to testing.

Specimen & Volume: Whole blood, serum, plasma, and/or urine

Container: Various (Call Special Pathogens lab for further instructions)

Shipping Description: Call Special Pathogens lab for further instructions

Storage/Shipping Temperature: Call Special Pathogens lab for further instructions

Rejection Criteria, specific: Call Special Pathogens lab for further instructions

Methodology: Real Time RT-PCR

Add. Information: Confirmation of positive samples will be made by the CDC.

CPT Code: NA

ECHOVIRUS - See "Enterovirus Culture"

E. COLI O157:H7 - See "Enteric Pathogens Culture"

ENCHINOCOCCOSIS - See "Parasite Serology"

ENTERIC GI PANEL by FilmArray (PCR)

Enteric GI Panel by FilmArray (PCR) testing is available for outbreaks (other than suspected Norovirus and Rotavirus outbreaks) as determined by the SC DHEC Division of Acute Disease Epidemiology.

Synonyms: Bacteria: *Campylobacter, Clostridium difficile* toxin A/B, *Plesiomonas shigelloides, Salmonella, Vibrio species, Vibrio cholerae, Yesrsina enterocolytica;* Diarrhegenic *E. coli/Shigella:* Enteroaggregative *E. coli* (EAEC), Enteropathogenic *E. coli* (EPEC), Enterotoxigenic *E. coli* (ETEC) It/st, Shiga-like toxin-producing *E. coli* (STEC) stx1/stx2, *E. coli* 0157, *Shigella/Enteroinvasive E. coli* (EIEC); Parasites: *Cyclospora cayetanensis, Crytosporidium, Entamoeba histolytica, and Giardia lamblia;* Viruses: Adenovirus F 40/41, Astrovirus, and Norovirus GI/GII, Rotavirus A, Sapovirus

Test Laboratory: Virology 803-896-0820

Days Test Performed: Monday – Friday **Note: <u>For same day test results, specimen must be received by noon.</u>**

Request Form: DHEC 1335, Test #508 and (specify)

Special Instructions: Call Virology Laboratory

Specimen & Volume: Walnut sized portion of feces or 5-10 ml of liquid stool
Infant specimens may be collected in a disposable diaper with plastic side facing inside.

ENTERIC GI PANEL by FilmArray (PCR) (Continued)

Container: Transport tube in Enteric Kit with Cary-Blair medium

Storage/Shipping Temperature: Ship on cold packs

Shipping Description: See **Packing and Shipping Instructions, Section IV.**

Rejection Criteria, specific: Unpreserved stool and specimen preserved in PVA. For universal rejections, See **Section I**

Methodology: FilmArray GI panel (PCR)

Add. Information: To detect the presence of enteric pathogens other than Norovirus in a GI outbreak situation.

CPT Code: 87507

ENTERIC PATHOGENS CULTURE

Enteric Pathogens culture testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology. Epidemiology to note on requisition slip which pathogens are suspected.

Synonyms: Fecal culture, stool culture, Enteric culture, *Salmonella* culture, *Shigella* culture, *Campylobacter* culture, *Vibrio* culture , TOXIN culture – for *Staphylococcus aureus*, *Bacillus cereus*, and *Clostridium perfringens*

Test Laboratory: Clinical Microbiology, 803-896-0805

Days Test Performed: Monday - Friday

Request Form: DHEC 1335, Test #508

Special Instructions: Notify Clinical Microbiology prior to submission of specimens for culture of *Salmonella Typhi*, Toxins, *Vibrio* species or *Yersinia entercolitica* to ensure specialized media is secured. See **Enteric Collection Procedure, Section III**

Specimen & Volume: Walnut sized portion of feces or 5-10 ml of liquid stool
Infant specimens may be collected in a disposable diaper with plastic side facing inside.

Container: Transport tube in Enteric Kit with Cary-Blair medium

Storage/Shipping Temperature: Stools not in medium must be shipped with cold packs to arrive in the laboratory and be inoculated within 24 hours of collection. If specimen is in transport medium, store and ship under refrigeration to be received at the lab within 48 hours of collection.

Shipping Description: See **Packing and Shipping Instructions, Section IV.** May use state courier for overnight delivery.

Rejection Criteria, specific: Quantity insufficient; specimen too old; improper transport media or conditions. For universal rejections, See **Section I**

Methodology: VITEK MS, Conventional culture methods and biochemicals; Serological tests for *Shigella*, *E. coli* BOTH non and 0157, *Vibrio species including cholera* and *Salmonella*; PCR also available (FilmArray GI panel)

Add. Information: NA

CPT Code: *Salmonella* and *Shigella* Culture 87045; all others 87046; ID 87077; PCR 87507

ENTERIC PATHOGENS SUBMITTED by NON-CULTURE INDEPENDENT METHODS (PCR)

Synonyms: Fecal culture, stool culture, Enteric culture, *Salmonella* culture, *Shigella* culture, *E. coli [Shiga-toxin producing (STEC)], E. coli (0157), Vibrio species,Campylobacter*

Test Laboratory: Clinical Microbiology, 803-896-0805

ENTERIC PATHOGENS SUBMITTED by NON-CULTURE INDEPENDENT METHODS (PCR) (Continued)

Days Test Performed: Monday - Friday

Request Form: DHEC 1335, Test #508

Special Instructions: Isolate all Salmonellas and Shigellas before submission. **Note:** Do not submit Raw Stools or Cary-Blair for isolation of Salmonella or Shigella Organisms. Submit Cary-Blair on cold packs if unable to obtain an isolate for *Shiga-toxin producing*, *E. coli* and *Vibrio species* and *Campylobacter*. See **Enteric Collection Procedure, Section III**

Specimen & Volume: *Salmonella* and *Shigella* isolates submit on slants

Container: Submit 1 ml minimum in transport medium, such as Cary-Blair. Submit a slant that will support *Salmonella* and *Shigella*, such as TSA, SBAP.

Storage/Shipping Temperature: Ship slants of *Salmonella a*nd *Shigella* at ambient temperature. Ship *Shiga-toxin producing* (E. coli), *Campylobacter* and *Vibrio species* in Cary-Blair on cold packs to be received in lab within 48 hours.

Shipping Description: See **Packing and Shipping Instructions, Section IV.** May use state courier for overnight delivery.

Rejection Criteria, specific: Quantity insufficient; specimen too old; improper transport media or conditions. For universal rejections, See **Section I**

Methodology: Conventional culture methods and biochemical, Vitek MS

Add. Information: NA

CPT Code: *Salmonella* and *Shigella* Culture 87045; all others 87046; ID 87077

ENTEROVIRUS CULTURE

Synonyms: Includes - ECHO, Coxsackie A & B

Test Laboratory: Virology/Rabies, 803-896-0819

Days Test Performed: Monday - Friday

Request Form: DHEC 1335, Test #270

Special Instructions: See **Viral Culture/Respiratory Culture/Herpes Culture Collection Procedure, Section III**

Specimen & Volume: Throat swab, rectal swab, N-P swab, feces, CSF

Container: Dry tube for feces, CSF collection tube, or tube of viral transport media for swab

Storage/Shipping Temperature: Store in refrigerator and ship cold with cold packs within 24-48 hours. If shipping is delayed, freeze specimen and ship on dry ice.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimen too old. For universal rejections, See **Section I**

Methodology: Cell culture

Add. Information: NA

CPT Code: Culture 87252; Identification 87253

EHRLICHIOSIS

Synonyms: NA

Test Laboratory: Referred to Centers for Disease Control and Prevention (CDC) for testing.

Days Test Performed: NA

Request Form: CDC specimen Referral Form 50.34 Rev 8-84

EHRLICHIOSIS (Continued)

Special Instructions: Please contact Amanda Moore prior to sending specimens to CDC for testing at 803-896-0777.

Specimen & Volume: EDTA blood, serum, CSF

Container: Purple top vacuum tube (EDTA), sterile container (CSF), See **Venipuncture Procedure, Section III,** if needed.

Storage/shipping Temperature: NA

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: None. For universal rejections, See **Section I**

Methodology: NA

Add. Information: NA

CPT Code: NA

ESCHERICIA COLI – SHIGA-TOXIN PRODUCING

Synonyms: *E. coli* O157:H7, *E.coli* non-O157:H7, STEC

Test Laboratory: Clinical Microbiology 803-896-0805

Days Test Performed: Monday – Friday.

Request Form: DHEC 1335, Test #503 for identification from stool or broth. Test #502 for referred isolates.

Special Instructions: Testing of stools for STEC requires consultation with, and approval by a DHEC Epidemiologist.

Specimen and Volume: Walnut sized portion of feces or 5-10 ml of liquid stool in Cary-Blair transport media (mix and tighten cap to prevent leaking) or raw stool in a clean, leak-proof container. Isolate - agar slant. Enrichment broths testing positive for shiga-toxin are also acceptable. Isolates sent on an agar slant.

Container: Transport tube in Enteric Kit with Cary-Blair medium

Storage/Shipping Temperature: Store Cary-Blair in refrigerator, ship stool preserved in Cary-Blair media on cold packs.
Ship raw stool on cold packs for arrival at the laboratory within 2 hours of collection. Enrichment broths (GN and MacConkey Broth) should be maintained in the refrigerator and shipped on cold packs as soon as possible to increase the odds of isolating the organism. Referred isolates can be shipped at ambient temperature.
Ship isolates as soon as isolated, maybe shipped at ambient temperature.

Shipping Description: See **Packing and Shipping Instructions, Section IV**. May use state courier for overnight delivery.

Rejection Criteria, specific: Improper transport media or conditions. For universal rejections, See **Section I**

Methodology: Conventional culture methods, biochemical analysis, and EIA or immunochromatographic rapid test for shiga-toxin.

Additional Information: NA

CPT Code: Culture 87046; ID 87077

FILARIASIS - See "Parasite Serology"

FOODBORNE ILLNESSES (FOOD POISONING)

The Food Laboratory assists in the epidemiological investigation of suspected foodborne illness. A physician with a patient suspected of having a foodborne illness should contact Food

Protection in the county health department. The laboratory does not accept samples from individuals.

FRANCISELLA TULARENSIS

Synonyms: Tularemia, rabbit fever, deerfly fever

Test Laboratory: Special Pathogens, 803-896-0777

Days Test Performed: As needed

Request Form: 1335, Test #520 or 521; Suspect agent "Francisella tularemia"

Special Instructions: This organism has been designated as a Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777, 803-767-8118, or 803-896-0773.

Specimen & Volume: Clinical samples, clinical isolates, and environmental samples (submitted by FBI)

Container: See Special Instructions Above

Storage/Shipping Temperature: See Special Instructions Above

Shipping Description: See Special Instructions Above

Rejection Criteria, specific: See Special Instructions Above

Methodology: A variety of sentinel and LRN methods are used to confirm or rule-out bacterial isolates.

Add. Information: NA

CPT Code: NA

GALACTOSEMIA - See "Newborn Screening Panel"

GC CULTURE - See "Gonococcal Culture"

GEN-PROBE ANTIGEN DETECTION - See "GC and Chlamydia antigen detection"

GERMAN MEASLES - See "Rubella Serology IgG and IgM"

GIARDIA ANTIGEN

Giardia antigen testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology.

Synonyms: NA

Test Laboratory: Clinical Microbiology, 803-896-0805

Days Test Performed: Monday - Friday

Request Form: DHEC 1335, Test #410 Other_____

Special Instructions: Test available only for outbreaks of public health importance as determined by a DHEC Epidemiologist.

Specimen & Volume: 10% formalin, Cary-Blair, C&S, or Stuart's transport media are the preferred media for specimen collection. Fresh (unpreserved) samples are also acceptable

Container: Leakproof tube or container

Storage/Shipping Temperature: Store and ship on cold packs.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimen preserved in PVA; improper labeling. For universal rejections, See **Section I**

GIARDIA ANTIGEN (Continued)

Methodology: Rapid immunoassay for the qualitative detection of *Giardia lambia* antigen and to detect the presence of *Cryptosporidium parvum.*

Add. Information: NA

CPT Code: 87329

GI OUTBREAK

GI Outbreak testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology.

Synonyms: Norwalk Virus, Norovirus PCR, Enteric Cuture, Rotavirus

Test Laboratory: Virology/Rabies, 803-896-0819

Days Test Performed: As needed

Request Form: DHEC 1335, Test #121

Special Instructions: Use of this test is restricted to Epidemiological investigations. This test should be used when a GI outbreak is suspected and multiple etiologies are suspected. Please contact your Regional Epidemiological contact.

Specimen & Volume: Two separate collections are required. See Norovirus Detection by Real-Time PCR and Enteric Pathogens Culture

Container: Two separate collections are required. See Norovirus Detection by Real-Time PCR and Enteric Pathogens Culture

Storage/Shipping Temperature: Store in refrigerator and ship on cold packs.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimen not cold on arrival; Specimen more than 7 days old when received. Quantity insufficient; specimen too old; improper transport media or conditions. For universal rejections, See **Section I**

Methodology: See Norovirus Detection by Real-Time PCR and Enteric Pathogens Culture

Add. Information: When ordering this test panel please write GI Outbreak on the submission form. This panel designates a testing algorithm for GI outbreaks of unknown etiology. This panel includes tests for norovirus rRT-PCR, Biofire FilmArray GI Panel, and enteric culture (in this order). Testing will cease when a positive identification is made. If enteric pathogens other than *Salmonella, E. coli* 0157:H7, or *Shigella* are suspected please specify.

CPT Code: Enteric Culture Pathogens: *Salmonella* and *Shigella* Culture 87045; all others 87046; ID 87077; Norovirus Detection by Real-Time PCR 87798

GONOCOCCAL (GONORRHEA) CULTURE

Restricted to County Health Departments only

Synonyms: GC culture, *Neisseria gonorrhoeae* culture

Test Laboratory: Clinical Microbiology, 803-896-0805

Days Test Performed: Monday – Wednesday

Request Form: DHEC 1335, Test #501

Special Instructions: Bring transgrow bottle to room temperature before inoculating**:** hold bottle upright and roll swab over entire surface of medium; discard swab. NOTE: Use the state courier for overnight delivery. Do not mail specimens for arrival over a weekend.

Specimen & Volume: See ***N. gonorrhoeae* Collection Procedure, Section III**

Container: Transgrow bottles DO NOT PLACE LABEL ON CLEAR SIDE OF BOTTLE

GONOCOCCAL (GONORRHEA) CULTURE (Continued)

Storage/Shipping Temperature: If an incubator is available, incubate inoculated transgrow bottle upright at 35° C until shipped, and indicate incubation time on request form.
If an incubator is not available, make sure culture is shipped on the same day as collected. DO NOT REFRIGERATE AFTER INOCULATION. **DO NOT USE EXPIRED MEDIA.**

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Transgrow media not used or media expired; specimen in transit more than 5 days. For universal rejections, See **Section I**

Methodology: VITEK MS, Carbohydrate fermentation or enzyme detection

Add. Information: NA

CPT Code: Culture 87070; Identification 87077

GONOCOCCAL (GC) DETECTION by NUCLEIC ACID AMPLIFICATION

Synonyms: Gen-Probe *N. gonorrhoeae* Amplified Nucleic Acid Probe, Gonorrhea rRNA, GC Aptima

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday-Friday

Request Form: DHEC 1332, Test #505-GC only; Test #507 - GC and Chlamydia

Special Instructions: Only use Gen-Probe Aptima specimen collection kit materials (unisex swab, vaginal, or urine). Patients under the age of twelve should be tested by culture.

Specimen & Volume: Swab specimen: Endocervical, validated rectal and pharyngeal swab, or male urethral Gen-Probe blue-shafted swab in Gen-Probe Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab specimens (Blue label). Vaginal samples: Use the Gen-Probe Aptima Vaginal Swab Specimen Collection Kit (Orange label) for collecting vaginal samples. Vaginal samples collected in the Aptima Unisex Swab Collection Kit will be disclaimed as not FDA approved for this type of specimen. Urine samples: Patient should not have voided within one hour of collection. Collect first 20-30 ml of the first-catch urine stream into collection cup. Transfer 2 ml of urine into Aptima Urine Specimen Transport tube so that the urine level falls within the two lines on the transport tube labeled: "fill area". (Yellow Label). See **GC/Chlamydia Gen-probe Collection Procedure, Section III**

Container: Gen-Probe Aptima Unisex transport kit for endocervical and male urethral swabs. Gen-Probe Aptima Urine specimen transport tubes for urine samples. Gen-Probe Aptima Vaginal Swab Specimen Collection kit for vaginal samples

Storage/Shipping Temperature: Store and ship at room temperature. Swab specimens must be tested within 60 days of collection. Urine specimens within 30 days of collection

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimen with no swab in transport media; white swab in transport media; two swabs in transport media; urine above or below designated black lines on transport tube labeled fill area; swab specimen more than 60 days old, or urine specimen more than 30 days old. For universal rejections, See **Section I**

Methodology: Target Amplification Nucleic acid Probe

Add. Information: This test is not appropriate in cases of sexual assault or abuse. Patients under the age of 12 should be tested by culture.

CPT Code: GC 87591; GC/CT 87491, 87591

HAEMOPHILUS INFLUENZAE

Synonyms: NA
Test Laboratory: Clinical Microbiology 803-896-0805
Days Test Performed: Monday – Friday.
Request Form: DHEC 1335, Test #511 (Organism for ID-aerobic/referred isolate). Sterile Sites
Special Instructions: Pure bacterial isolate on agar slant (chocolate agar is preferred).
Specimen and Volume: Pure bacterial isolate on an agar slant that will support the growth of the isolate.
Container: Screw-capped tube, containing agar slant that will support growth of isolate
Storage/Shipping Temperature: Store in a 35°C (CO_2) incubator and ship at room temperature.
Shipping Description: See **Packing and Shipping Instructions in Section IV**. May use state courier for overnight delivery.
Rejection Criteria, specific: Culture non-viable; culture mixed. For universal rejections, **See Section I**
Methodology: VITEK MS, Conventional culture methods and biochemical analysis.
Additional Information: NA
CPT Code: Culture 87046; ID 87077

HEMOGLOBIN (Hb) ELECTROPHORESIS

Synonyms: Sickle Cell screen
Test Laboratory: Newborn Screening, 803-896-0874
Days Test Performed: Monday - Friday
Request Form: DHEC 1339 (Adult hemoglobin form)
Special Instructions: NA
Specimen & Volume: Blood spots on approved filter paper
Container: Approved filter paper on the DHEC 1339 (Adult hemoglobin form)
Storage/Shipping Temperature: Store and ship at room temperature. Do NOT mail specimens in any type of plastic bag or packaging, or polymer-lined mailing envelope.
Shipping Description: See **Packing and Shipping Instructions, Section IV, "Shipping Newborn Screening Blood Spots"**
Rejection Criteria, specific: Patient transfused within the last 120 days; Specimens that are scratched, abraded, clotted, layered, contaminated, quantity insufficient; specimens that are older than 14 days; specimens that are collected on an expired collection form; specimens that are shipped in a plastic bag, in a polymer-lined or bubble-wrap-lined envelope.
Methodology: Iso Electric Focusing (IEF); High Performance Liquid Chromatography (HPLC)
Add. Information: NA
CPT Code: 83020

HEMATOLOGY- See "CBC"

HEMOLYTIC ANEMIA - See "Hemoglobin Electrophoresis"

HEPATITIS A SEROLOGY

Synonyms: HAVAB-G; Anti-HAV; HAVAB-IgG; Antibody to Hepatitis HAV-IgG; Anti-HAV, IgG; Antibody to Hepatitis A Virus, IgG; HAVAB-M; HAVAB-IgM; Antibody to HAV-IgM; Anti-HAV, IgM; Antibody to Hepatitis A Virus, IgM

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Upon request; See Special Instructions.

Request Form: DHEC 1332, Test #019- Hepatitis A, IgG; Test #020- Hepatitis A, IgM

Special Instructions: All Hepatitis A outbreak investigations should be reported to the laboratory supervisor (803-896-0811) or Division Director (803-896-0870) prior to shipment of specimens. After collecting the sample invert the serum-separator tube gently 5 times, allow to clot for at least 30 minutes and centrifuge within 2 hours from the time of collection. Samples **must be centrifuged within 2 hours** of collection to separate the serum from the clot.

Specimen & Volume: 0.50 ml of serum; See **Venipuncture Collection Procedure, Section III**, if needed.

Container: Serum-separator tube or serum. (Red top vacuum tubes may **only be used if** the sample is sent in within 24 hours or centrifuged and serum is removed from the clot and put into a different container/tube.)

Storage/Shipping Temperature: It is acceptable to ship specimens for anti-HAV (IgG) and anti-HAV (IgM) tests at ambient temperature as long as the specimen is received in the lab within **3 days** of collection. If it will be more than 3 days, store at 2-8°C following specimen collection and ship with an ice pack. If shipping is delayed more than 7 days, remove the serum from the clot or gel and freeze the serum at -20ºC and ship on dry ice. Before shipping specimens, it is recommended that specimens be removed from the clot, red blood cells or separator gel. *If the specimen is frozen prior to shipment, please indicate this information on the request form. Anti-HAV (IgG) samples containing low antibody concentrations (near the cutoff) assayed after a freeze thaw may exhibit elevated values that may be false positive.*

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens will be rejected. Specimen greater than 7 days old when received, unless the serum was frozen and shipped on dry ice will be rejected. Please indicate if the specimen was frozen on the requisition form. Specimen shipped in ambient conditions that are greater than 3 days old when received, will not be tested and will be rejected, unless the sample was refrigerated and received on a cold pack. A second specimen will need to be collected if any samples are rejected. For universal rejections, see **Section I.**

Methodology: Chemiluminescence

Add. Information: A positive HAV IgG antibody result indicates a past or current HAV infection. A positive HAV IgM antibody indicates an acute HAV infection, one that is usually accompanied by clinical symptoms of acute hepatitis. The clinical symptoms of HAV may precede the laboratory detection of HAV IgM by a few days.

CPT Code: Total 86708; IgM 86709

HEPATITIS B CORE TOTAL ANTIBODY SCREEN

Synonyms: Anti-HBc; Core Antibody; HBcAb, Total; Antibody to Hepatitis B Core Antigen

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday - Friday

Request Form: DHEC 1332, Test #226

Special Instructions: After collecting the sample invert the serum-separator tube gently 5 times, allow to clot for at least 30 minutes and centrifuge within 2 hours from the time of collection. Samples **must be centrifuged within 2 hours** of collection to separate the serum from the clot. See

HEPATITIS B CORE TOTAL ANTIBODY SCREEN (Continued)

Venipuncture Procedure, Section III, if needed.

Specimen & Volume: 0.5 ml serum

Container: Serum-separator tube or serum. (Red top vacuum tubes may **only be used if** the sample is sent in within 24 hours or centrifuged and serum is removed from the clot and put into a different container/tube.)

Storage/Shipping Temperature: EXCLUDING HBsAG, it is acceptable to ship specimens at ambient temperature as long as the specimen is received in the lab within **3 days** of collection. If it will be more than 3 days, store at 2 to 8˚C following specimen collection and ship with an ice pack. If shipping is delayed more than 7 days, remove the serum from the clot or gel and freeze the serum at -20° C and ship on dry ice. Before shipping specimens, it is recommended that specimens be removed from the clot, red blood cells, or separator gel. *If you have frozen the specimen prior to shipment, please indicate this information on the request form.*

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens will be rejected. Specimen greater than 7 days old when received, unless the serum was frozen and shipped on dry ice will be rejected. Please indicate if the specimen was frozen on the requisition form. Specimen shipped in ambient conditions that are greater than 3 days old when received, will not be tested and will be rejected, unless the sample was refrigerated and received on a cold pack. A second specimen will need to be collected if any samples are rejected. For universal rejections, see **Section I.**

Methodology: Chemiluminescence

Add. Information: NA

CPT Code: 86704

HEPATITIS B DIAGNOSTIC PROFILE

Synonyms: NA

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday - Friday

Request Form: DHEC 1332, Test #223

Special Instructions: After collecting the sample invert the serum-separator tube gently 5 times, allow to clot for at least 30 minutes and centrifuge within 2 hours of collection. Samples **must be centrifuged within 2 hours** of collection to separate the serum from the clot. See **Venipuncture Procedure, Section III,** if needed.

Specimen & Volume: 2 ml serum

Container: Serum-separator tube or serum. (Red top vacuum tubes may **only be used if** the sample is sent in within 24 hours or centrifuged and serum is removed from the clot and put into a different container/tube.) *Please follow manufacturer's guidelines.*

Storage/Shipping Temperature: **Store refrigerated (2- 8°C) and ship on ice.** Specimen must arrive at lab **cold and within 6 days** of collection. If shipping is delayed more than **6** days, freeze serum and ship on dry ice. *NOTE: If you have frozen the specimen prior to shipment, please note that you have done so on the request form.*

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: "Specimens submitted for HBsAg **MUST** be shipped on an ice pack." Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens will be rejected. Specimen greater than 6 days old when received, unless the serum was frozen and shipped on dry ice, will be rejected. *Please indicate if the specimen was frozen on the requisition form.* Specimen shipped in ambient conditions will not be tested and will be rejected,

HEPATITIS B DIAGNOSTIC PROFILE (Continued)

samples must be refrigerated and received on a cold pack. A second specimen will need to be collected if any samples are rejected. For universal rejections, see **Section I.**

Methodology: Chemiluminescence

Add. Information: Includes tests for HBsAg, anti-HBs, and anti-HBc, and anti-core IgM are performed if indicated.

Interpretations:

HbsAg	anti-HBs	Anti-HBc total antibody	Interpretation
-	-	-	No laboratory evidence of HBV infection. Does not rule-out "low level" HBV carrier state, or the" window" between the disappearance of HBsAg and the appearance of anti-HBs and anti-HBc IgG.
+	-	-	Early acute HBV infection.
+	±	+	HBV infection, either acute or chronic. Differentiate with anti-HBc IgM.
-	+	+	Previous HBV infection and immunity to HBV.
-	+	-	Vaccine-type response indicating immunity to HBV.

CPT Code: Surface Antigen 87340; Surface Antibody 86706; Core Antibody 86704

HEPATITIS B CORE IgM ANTIBODY

Test automatically performed on patients with reactive anti-HBc total antibody in absence of reactive HBsAg or anti-HBs on Diagnostic Profile (test #223) and test automatically performed on patients with reactive Hepatitis B surface antigen on Diagnostic Test Panel #223

Synonyms: Anti-HBc, IgM; HBcAb,IgM; Antibody to Hepatitis B Core Antigen, IgM

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Available upon request. See special instructions below.

Request Form: DHEC 1332, Test #220

Special Instructions: See **Venipuncture Procedure, Section III**, if needed.

Specimen & Volume: 0.25 ml serum

Container: Serum-separator tube or serum. (Red top vacuum tubes may **only be used if** the sample is sent in within 24 hours or centrifuged and serum is removed from the clot and put into a different container/tube.)

Storage/Shipping Temperature: EXCLUDING HBsAG, it is acceptable to ship specimens at ambient temperature as long as the specimen is received in the lab within **3 days** of collection. If it will be more than 3 days, store at 2 to 8˚C following specimen collection and ship with an ice pack. If shipping is delayed more than 7 days, remove the serum from the clot or gel and freeze the serum at -20° C and ship on dry ice. Before shipping specimens, it is recommended that specimens be removed from the clot, red blood cells, or separator gel. *If you have frozen the specimen prior to shipment, please indicate this information on the request form.*

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: "Specimens submitted for HBsAg **MUST** be shipped on an ice pack." Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens will be rejected. Specimen greater than 6 days old when received, unless the serum was frozen and shipped on dry ice, will be rejected. Please indicate if the specimen was frozen on

HEPATITIS B CORE IgM ANTIBODY (Continued)

the requisition form. Specimen shipped in ambient conditions that are greater than 24 hours old when received, will not be tested and will be rejected, unless the sample was refrigerated and received on a cold pack. A second specimen will need to be collected if any samples are rejected. For universal rejections, see **Section I.**

**Test automatically performed on patients with reactive anti-HBc total antibody in absence of reactive HBsAg or anti-HBs on Diagnostic Profile (test #223) and test automatically performed on patients with reactive Hepatitis B surface antigen on Diagnostic Test Panel #223* must* arrive at lab within 6 days of collection. If shipping is delayed more than 6 days, freeze serum and ship on dry ice. *NOTE: If you have frozen the specimen prior to shipment, please indicate that you have done so on the request form.*

Methodology: Chemiluminescence

Add. Information: A positive Anti-HBc IgM result in conjunction with a positive hepatitis B surface antigen result indicates an early acute HBV infection

CPT Code: 86705

HEPATITIS B IMMUNE STATUS/POST-IMMUNIZATION

Synonyms: Anti-HBs and Anti-HBc

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday - Friday

Request Form: DHEC 1332, Test #222

Special Instructions: Tests includes Anti-HBs and Anti-HBc

Specimen &Volume: 1 ml serum

Container: Serum-separator tube or serum. (Red top vacuum tubes may **only be used if** the sample is sent in within 24 hours or centrifuged and serum is removed from the clot and put into a different container/tube.) See **Venipuncture Procedure, Section III**, if needed.

Storage/Shipping Temperature: EXCLUDING HBsAG, it is acceptable to ship specimens at ambient temperature as long as the specimen is received in the lab within **3 days** of collection. If it will be more than 3 days, store at 2 to 8˚C following specimen collection and ship with an ice pack. If shipping is delayed more than 7 days, remove the serum from the clot or gel and freeze the serum at -20° C and ship on dry ice. Before shipping specimens, it is recommended that specimens be removed from the clot, red blood cells, or separator gel. *If you have frozen the specimen prior to shipment, please indicate this information on the request form.*

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: : "Specimens submitted for HBsAg **MUST** be shipped on an ice pack." Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens will be rejected. Specimen greater than 6 days old when received, unless the serum was frozen and shipped on dry ice, will be rejected. Please indicate if the specimen was frozen on the requisition form. Specimen shipped in ambient conditions that are greater than 24 hours old when received, will not be tested and will be rejected, unless the sample was refrigerated and received on a cold pack. A second specimen will need to be collected if any samples are rejected. For universal rejections, see **Section I.**

Methodology: Chemiluminescence

Add. Information: NA

CPT Code: Surface antibody 86706; Core antibody 86704

HEPATITIS B SURFACE ANTIBODY

Synonyms: HBsAb; Anti-HBs; Antibody to Hepatitis B Surface Antigen

Test Laboratory: Diagnostic Serology, 803-896-0811

HEPATITIS B SURFACE ANTIBODY (Continued)

Days Test Performed: Monday – Friday

Request Form: DHEC 1332, Test #228

Special Instructions: None

Specimen & Volume: 2 mL whole clotted blood, or 1 mL of serum

Container: Serum-separator tube or serum. (Red top vacuum tubes may **only be used if** the sample is sent in within 24 hours or centrifuged and serum is removed from the clot and put into a different container/tube.) See **Venipuncture Procedure, Section III**, if needed.

Storage/Shipping Temperature EXCLUDING HBsAG, it is acceptable to ship specimens at ambient temperature as long as the specimen is received in the lab within **3 days** of collection. If it will be more than 3 days, store at 2 to 8˚C following specimen collection and ship with an ice pack. If shipping is delayed more than 7 days, remove the serum from the clot or gel and freeze the serum at -20° C and ship on dry ice. Before shipping specimens, it is recommended that specimens be removed from the clot, red blood cells, or separator gel. *If you have frozen the specimen prior to shipment, please indicate this information on the request form.*

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: "Specimens submitted for HBsAg **MUST** be shipped on an ice pack." Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens will be rejected. Specimen greater than 6 days old when received, unless the serum was frozen and shipped on dry ice, will be rejected. Please indicate if the specimen was frozen on the requisition form. Specimen shipped in ambient conditions that are greater than 24 hours old when received, will not be tested and will be rejected, unless the sample was refrigerated and received on a cold pack. A second specimen will need to be collected if any samples are rejected. For universal rejections, see **Section I.**

Methodology: Chemiluminescence **Add. Information:** NA

CPT Code: 86706

HEPATITIS B SURFACE ANTIGEN

Synonyms: HBsAg; Hepatitis-Associated Antigen

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday – Friday

Request Form: DHEC 1332, Test #225

Special Instructions: None

Specimen & Volume: 1 ml serum

Container: Serum-separator tube or serum. (Red top vacuum tubes may **only be used if** the sample is sent in within 24 hours or centrifuged and serum is removed from the clot and put into a different container/tube.) See **Venipuncture Procedure, Section III**, if needed.

Storage/Shipping Temperature: Store refrigerated (2° - 8°C) and ship on ice. Specimen must arrive at lab within **6** days of collection. If shipping is delayed more than **6** days, freeze serum and ship on dry ice. *NOTE: If you have frozen the specimen prior to shipment, please note that you have done so on the request form.*

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: "Specimens submitted for HBsAg **MUST** be shipped on ice pack." Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens will be rejected. Specimen greater than 6 days old when received, unless the serum was frozen and shipped on dry ice, will be rejected. Please indicate if the specimen was frozen on the requisition form. Specimen shipped in ambient conditions will not be tested and will be rejected, unless the sample was refrigerated and received on a cold pack. A second specimen will need to be collected if any samples are rejected. For universal rejections, see **Section I.**

HEPATITIS B SURFACE ANTIGEN (Continued)

Methodology: Chemiluminescence

Add. Information: NA

CPT Code: 87340

HEPATITIS C, TOTAL ANTIBODY

Synonyms: Antibody to Hepatitis C Virus; Anti-HCV

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday-Friday.

Request Form: DHEC 1332, Test #224

Special Instructions: For sites requesting **HCV RNA** if total antibody reactive by EIA, collect blood in a serum separator tube, spin down within 2 hours of collection, and ship cold with cold packs to arrive **within 24 hours** of collection. If sample cannot be shipped within 24 hours, store refrigerated and ship within 5 days. Sample must arrive with a requisition stating it was kept refrigerated. Label outside of box HCV Viral Load with indelible marker or sticker that cannot easily be removed. Viral loads can be shipped with any STD sample, but MUST have an ice pack in the biohazard bag with the tube. The sample MUST stay cold at all times during transport.

Specimen & Volume: 0.25 ml serum (if reactive, a total of 2.25 ml serum needs to be collected and sent for confirmatory testing)

Container: Serum-separator tube or serum. (Red top vacuum tubes may **only be used if** the sample is sent in within 24 hours or centrifuged and serum is removed from the clot and put into a different container/tube.) See **Blood Collection Procedure for HCV, Section III**

Storage/Shipping Temperature: For sites requesting **HCV RNA** if total antibody reactive by EIA, collect blood in a serum separator tube, spin down within 2 hours of collection, and ship cold with cold packs to arrive **within 24 hours** of collection. If sample cannot be shipped within 24 hours, please store at 2-8C for up to 4 days. Sample must arrive within 5 days of collection and must have been refrigerated the whole time. If it will be more than 5 days, separate serum from the clot or gel and freeze in a secondary container. Label outside of box HCV Viral Load with indelible marker or sticker that cannot easily be removed.

It is acceptable to ship specimens ambient as long as the specimen is received in the lab within **3 days** of collection and if viral load testing is not required. (It is better to follow the HCV RNA guideline for storage in case a sample is reactive so that it can be confirmed.) If it will be more than 3 days, store at 2 to 8˚C following specimen collection and ship with an ice pack. If shipping is delayed more than 7 days, remove the serum from the clot or gel and freeze the serum at -20° C and ship on dry ice. Before shipping specimens, it is recommended that specimens be removed from the clot, red blood cells, or separator gel. *If you have frozen the specimen prior to shipment, please indicate this information on the request form.*

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens will be rejected. (Test #224 only) Specimen received greater than 7 days old, unless the serum was frozen and shipped on dry ice will be rejected. Please indicate if the specimen was frozen on the requisition form. Specimen shipped in ambient conditions that are greater than 3 days old when received, will not be tested and will be rejected, unless the sample was refrigerated and received on a cold pack. A second specimen will need to be collected if any samples are rejected. For universal rejections, see **Section I.**

Methodology: Chemiluminescence

Add. Information: Interpretation: Positive HCV Total Antibody results will be confirmed using the HCV Viral Load test as long as the **Special Instructions** listed above are followed.

HEPATITIS C, QUANTITATION BY PCR (RNA)

CPT Code: 86803

Synonyms: HCV Viral Load test

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday-Thursday

Request form: DHEC 1332, Test #227

Special Instructions: Collect blood in a serum separator tube, allow to clot for at least 30 minutes, **spin down within 2 hours of collection**, and ship cold with cold packs to arrive **within 5 days** of collection (please send in as soon as possible even though sample is viable for a longer period of time). The sample MUST BE kept refrigerated at all times. Label outside of box HCV Viral Load with indelible marker or sticker that cannot easily be removed. Viral loads can be shipped with any STD sample, but MUST have an ice pack in the biohazard bag with the tube. The sample MUST stay cold at all times during transport.

Specimen & Volume: Minimum 2 ml serum; use serum separator tube and collect a full 6 ml of blood. See **Blood Collection Procedure for HCV, Section III**

Container: Serum separator tube

Storage/Shipping Temperature: Transport on cold packs in a container with return mailing address and the word **HCV** printed on the outside of the container; use enough cold packs to maintain a temperature between 2°-8 °C during transport. **Specimen must arrive at the laboratory within 24 hours or be stored between 2˚-8˚C and must arrive within 5 days from the date of collection on an ice pack. The requisition must also state that the sample was kept refrigerated. Please make sure to ship as soon as possible and do not collect if holiday will prevent sample from arriving within 5 days. If sample will not arrive within 5 days, remove serum from clot or gel and freeze. Send as soon as possible, send on dry ice and write on request form that the sample has been frozen.** Viral loads can be shipped with any STD sample, but MUST have an ice pack in the biohazard bag with the tube. The sample MUST stay cold at all times during transport.

Shipping Description: Infectious substance See **Packing and Shipping Instructions, Section IV** **Rejection Criteria, specific:** Serum separator tube not used or the sample is not cold upon arrival. For universal rejections, See **Section I**

Methodology: Nucleic acid amplification test (RT-TMA)

Add. Information: The measurable reportable range for this procedure is 10-10,000,000 IU/mL and 1.00-7.0 log 10; Specimens testing within this range will be reported as the measured IU/mL value and the log 10 value of the measured IU/mL value e.g. 30,000 IU/mL and 4.48 log 10. Specimens testing above 10,000,000 will be reported as > 10,000,000 IU/ mL and >7.0 log 10. Specimens testing less than 10 IU/mL and less than 1.00 log 10 will be reported as less than < 10 IU/mL as and less than < 1.00 log 10. Specimens with Not Detected will be reported as Not Detected.

CPT Code: 87522

HERPES SIMPLEX CULTURE

Synonyms: Herpes Virus Culture

Test Laboratory: Virology/Rabies, 803-896-0819

Days Test Performed: Monday - Friday

Request Form: DHEC 1335, Test #250

Special Instructions: DO NOT freeze specimen at -20 ºC. See **Viral Culture/Respiratory Culture/Herpes Culture Collection Procedure, Section III**

Specimen & Volume: Throat swab, NP swab, Cervical/vaginal swabs, Surface lesions or Tissue (small piece of fresh, unfixed); CSF

HERPES SIMPLEX CULTURE (Continued)

Container: Viral transport media (available upon request)

Storage/Shipping Temperature: Store in refrigerator and ship cold or at room temperature.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Calcium alginate swab used. For universal rejections, See **Section I**

Methodology: Virus ID by Enzyme linked Virus Inducible System

Add. Information: NA

CPT Code: Screen 87255; Identification 87140

Hg, Pb, Cd SCREEN IN BLOOD

Synonyms: NA

Test Laboratory: Analytical Chemistry, 803-896-0886

Days Test Performed: Twice per week

Request Form: DHEC 1332, Test #882

Special Instructions: None

Specimen & Volume: Minimum 2 mL EDTA whole blood from venipuncture

Container: Purple/lavender top EDTA tube

Storage/Shipping Temperature: Store and ship on cold packs at 4°C. Refrigerate specimen at 4ºC if shipping is delayed.

Shipping Description: See **Packaging and Shipping Instructions, Section IV.**

Rejection Criteria, Specific: Clotted blood, insufficient quantity (QNS). For universal rejections, See **Section I**.

Methodology: Inductively Coupled Plasma Mass Spectrometry

Add. Information: ≥5µg/dL is considered elevated in children less than 6 years of age. Action levels for blood lead in children and adults print on result reports. There are no established action levels for mercury or cadmium. The CDC currently recommends using the 95% upper limit from the NHANES study as action levels for mercury and cadmium.

CPT Code: Mercury 83015; Lead 83655; Cadmium 82300

HIV-1 PCR QUANTITATIVE (RNA)

Synonyms: HIV-1 Viral Load test

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday-Friday

Request Form: DHEC 1332, Test #231

Special Instructions: **The sample MUST BE kept refrigerated at all times.** Label outside of container as HIV (VIRAL LOAD). **Make sure label will not come off.**

Specimen & Volume: Minimum 2.0 mL EDTA anticoagulated plasma, See **Venipuncture Procedure, Section III**, if needed. If using EDTA vacutainer, separate the plasma from the packed cells within 2 hours of collection by centrifugation for 20 minutes at room temperature. Remove the plasma from the cells using a sterile transfer pipette to a sterile polypropylene transport tube. **Note:** Remove as much of the plasma from the cells as possible without aspirating cells **The assay requires 1.0 ml of plasma**. The PPT separator tube can be shipped **after centrifugation** without transferring plasma to another tube. Invert tube after centrifugation to insure complete separation of cells from plasma. If cells present in plasma, re-centrifuge before shipping.

HIV-1 PCR QUANTITATIVE (RNA) (Continued)

Container: PPT vacutainer (supplied by the Public Health Laboratory call 803-896-0913 to order) or polypropylene tube to which plasma cells have been transferred from the Lavender top (EDTA) vacuum tube or K2 EDTA with gel separator

Storage/Shipping Temperature: Transport on cold packs in a container with return mailing address and the word **HIV-1** printed on the outside of the container; use enough cold packs to maintain a temperature between 2°-8 °C during transport. **Specimen must arrive at the Laboratory within 3 days after collection. If it will be more than 3 days, transfer plasma into a secondary container and freeze the plasma. Please check with laboratory during a holiday to ensure that it will arrive within 3 days or inform them that the sample was frozen and shipped on dry ice. If stored refrigerated, please indicate this on the requisition or the sample will be rejected if over the 24 hour mark.** Viral loads can be shipped with any STD sample, but MUST have an ice pack in the biohazard bag with the tube. The sample MUST stay cold at all times during transport.

Shipping Description: Infectious substance See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Whole clotted blood, sample received after 3 days not frozen or not cold, and sample not separated upon arrival. For universal rejections, See **Section I**

Methodology: Nucleic acid amplification test

Add. Information: Therapeutic monitoring of HIV infection

Interpretation: The measurable reportable range for this procedure is 30-10,000,000 copies/ml and 1.47-7.0 log 10; Specimens testing within this range will be reported as the measured copy value and the log 10 value of the measured copy value e.g. 30,000 copies/mL and 4.48 log 10. Specimens testing above 10,000,000 will be reported as > 10,000,000 copies/ ml and >7.0 log 10 . Specimens testing less than < 30 copies/ml and less than < 1.47 log 10 will be reported as less than < 30 copies/ml and less than <1.47 log 10. Specimens with Not Detected will be reported as Not Detected.

CPT Code: 87536

HIV-1/HIV-2 SEROLOGY

Synonyms: HIV-1/HIV-2 antibody, HIV-1, HIV-2 antibodies, HIV-1 antigen

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday – Friday

Request Form: DHEC 1332, Test #230 HIV-1/HIV-2(Screen only), Test #234 HIV-1/HIV-2 and Geenius HIV 1 /2 Supplemental Assay, Test # 235 HIV-1/HIV-2 and STS (Reagin)

Special Instructions: After collecting the sample invert the serum-separator tube gently 5 times, allow to clot for at least 30 minutes and centrifuge within 2 hours from the time of collection. Please see "" for specific manufacturer's guidelines.

Specimen & Volume: 1 ml serum or plasma

Container: Serum Separator Tubes. (Red top vacuum tubes may **only be used if** the sample is sent in within 24 hours or centrifuged and serum is removed from the clot and put into a different container/tube.) See **Venipuncture Procedure**, **Section III**, if needed.

Storage/Shipping Temperature: It is acceptable to ship specimens for HIV-1/HIV-2 antibody screening tests at ambient temperature as long as the specimen is received to the lab within **2 days** of collection. If more than 2 days, store at 2 to 8˚C following specimen collection and ship with an ice pack. If shipping is delayed more than 7 days, remove the serum from the clot or gel and freeze the serum at -20° C and ship on dry ice.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimen greater than 7 days old when received, unless the serum was frozen and shipped on dry ice. Please indicate if the specimen was frozen on the requisition form. Specimen shipped in ambient conditions that are greater than 2 days old when received, will not be tested and will be

HIV-1/HIV-2 SEROLOGY (Continued)

rejected, unless the sample was refrigerated and received on a cold pack. A second specimen will need to be collected if any samples are rejected. For universal rejections, see **Section I.**

Methodology: Chemiluminescent Microparticle Immunoassay (CMIA) for HIV Ag/Ab, Geenius HIV 1 /2 , and STS Reagin for Syphilis

Add. Information: Interpretation: Repeat reactive specimens are confirmed by Geenius HIV 1 /2; Recommend repeat testing on all first-time positive patient results including CD4 and Viral load (HIV-1 RNA)

CPT Code: EIA 87389; Geenius HIV 1 /2 Supplemental Assay 86689; RPR 86592

HIV-1 SEROLOGICAL MONITORING- See "Lymphocyte Subset"

HUMAN METAPNEUMOVIRUS (hMPV)- See "Respiratory Viral Culture"

HYPOTHYROIDISM - See "Newborn Screening" for neonatal

INFLUENZA A: H5N1 (ASIAN CLAVE)

Synonyms: Avian Flu / Bird Flu

Test Laboratory: Special Pathogens, 803-896-0777, 803-896-0773

Days Test Performed: As needed

Request Form: 1335, Test #521; Suspect agent "Influenza A:H5N1"

Special Instructions: This organism has been designated as a Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777, 803-767-8118, or 803-896-0773. Specimen must be pre-approved by Special Pathogens department prior to testing.

Specimen & Volume: Throat swabs, Nasal washings/aspirates, nasopharyngeal swabs, sputum, bronchoalveolar lavage, tracheal aspirates, and bronchial washing.

Container: Various (Call Special Pathogens lab for further instructions)

Storage/Shipping Temperature: Call Special Pathogens lab for further instructions

Shipping Description: Call Special Pathogens lab for further instructions

Rejection Criteria, specific: Call Special Pathogens lab for further instructions

Methodology: Real Time RT-PCR

Add. Information: Testing for Influenza A:H5N1 will be concurrent with Influenza A:H7N9 testing

CPT Code: NA

INFLUENZA A: H7N9 (EURASIAN LINEAGE)

Synonyms: Avian Flu / Bird Flu

Test Laboratory: Special Pathogens, 803-896-0777, 803-896-0773

Days Test Performed: As needed

Request Form: 1335, Test #521; Suspect agent "Influenza A:H7N9"

Special Instructions: This organism has been designated as a Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777, 803-767-8118, or 803-896-0773. Specimen must be pre-approved by Special Pathogens department prior to testing.

Specimen & Volume: Throat swabs, Nasal washings/aspirates, nasopharyngeal swabs, sputum,

INFLUENZA A: H7N9 (EURASIAN LINEAGE) (Continued)

bronchoalveolar lavage, tracheal aspirates, and bronchial washing.

Container: Various (Call Special Pathogens lab for further instructions)

Storage/Shipping Temperature: Call Special Pathogens lab for further instructions

Shipping Description: Call Special Pathogens lab for further instructions

Rejection Criteria, specific: Call Special Pathogens lab for further instructions

Methodology: Real Time RT-PCR

Add. Information: Testing for Influenza A: H7N9 will be concurrent with Influenza A: H5N1 testing

CPT Code: NA

INFLUENZA DETECTION BY REAL-TIME (RT) PCR

Synonyms: Influenza Surveillance, Influenza Isolation, Influenza Detection

Test Laboratory: Virology & Rabies, 803-896-0819/803-896-0820

Days Test Performed: Monday-Friday

Request Form: DHEC 1335, Test #271

Special Instructions: Year round the Public Health Laboratory participates in the World Health Organization's (WHO) Influenza Surveillance Program. Collection kits are provided. Please contact the Virology laboratory for more information at 803-896-0819/803-896-0820. If Influenza A/H5N1, A/H7, or a newly emerging highly pathogenic human influenza strain is suspected, please contact your regional public health office for consultation. Contact information for the regional public health offices are located on the back of the South Carolina List of Reportable Diseases. Upon testing approval, please contact the DHEC Public Health Laboratory at 803-896-0777 or 803-896-8118 for specimen collection, storage and transportation. Testing for A/H5N1, A/H7, and for newly emerging highly pathogenic influenza strains is provided by the Special Pathogens Laboratory.

Specimen & Volume: Nasophargyngeal swabs (NPS), nasal aspirates (NA), nasal washes (NW), dual nasopharyngeal/throat swabs (NP/TS), throat swabs (TS), bronchoalaveolar lavage (BAL), bronchial wash (BW), tracheal aspirate (TA), and sputum (SPT) placed in 2-3 mL viral transport media.

Container: Screw-capped tube of viral transport media

Storage/Shipping Temperature: Store in refrigerator (2-8°C) and ship with cold packs within 72 hours of collection, or if longer, freeze samples at -70°C before shipping.

Shipping Description: Send to the attention of the Virology & Rabies laboratory. See **Packing and Shipping Instructions, Section IV**

Rejection Criteria: Specimens received on calcium alginate swabs, cotton swabs, or swabs with wooden shafts. For universal rejections, See **Section I.**

Methodology: Real-time reverse transcription polymerase chain reaction (real-time RT-PCR)

Additional Information: Influenza testing also includes a full-respiratory viral panel to identity other respiratory viral pathogens.

CPT Code: NA

LEAD, BLOOD

Synonyms: Blood Lead

Test Laboratory: Analytical Chemistry, 803-896-0886

Days Test Performed: Twice per week

Request Form: DHEC 1332, Test #852

LEAD, BLOOD (Continued)

Special Instructions: None

Specimen & Volume: 500 µl EDTA whole blood from finger stick or heel stick for screening; Venipuncture preferred for confirmation of an elevated level; Minimum acceptable volume is 2 ml EDTA whole from venipuncture; 500 µL for finger stick or heel stick See **Blood Lead Collection Procedures, Section III**

Container: Purple/lavender top vacuum tube, or purple/lavender Microtainer for finger or heel stick

Storage/Shipping Temperature: Store and ship at room temperature. Refrigerate specimen at 4ºC if shipping is delayed.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Clotted blood, insufficient quantity (QNS). For universal rejections, See **Section I**

Methodology: Inductively Coupled Plasma Mass Spectrometry

Add. Information: ≥5µg/dL is considered elevated in children less than 6 years of age. Action levels for blood lead in children and adults are printed on results report. Screening (fingerstick) levels ≥5µg/dL require venipuncture confirmation.

CPT Code: 83655

LEGIONELLA URINARY ANTIGEN TEST

Test available only for Division of Acute Disease Epidemiology (DADE)

Synonyms: Lateral-flow immunoassay for Legionella pneumophila serogroup 1 antigen in human urine specimens

Test Laboratory: Clinical Microbiology, 803-896-0805

Days Test Performed: Monday-Friday

Request Form: DHEC 1335, Test Other (test name)

Special Instructions: Human Urine samples, Unpreserved: Samples should be received in an airtight transport container and stored at 2-8°C. Samples should be tested as soon as possible, but may be held up to seven days at 2-8°C. Test available only for outbreaks of Public Health importance as determined by a DHEC Epidemiologist.

Specimen & Volume: 1 ml or > of Urine collected in either airtight transport container or airtight Boric Acid Urine Tube

Container: Leak-proof container

Storage/Shipping Temperature: Store in refrigerator and ship cold with cold packs.

Shipping Description: Urine is considered Infectious substance. See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Improper transport media or conditions. For universal rejections, See **Section I**

Methodology: Rapid, lateral-flow immunoassay for the qualitative detection of *Legionella pneumophila* serogroup 1 antigen in human urine specimens. It is designed to test specimens from patients with symptoms of pneumonia. Test results are to be used as an aid in diagnosis of *Legionella pneumophila* serogroup 1 infection. A negative result does not preclude infection with *Legionella pneumophila* serogroup 1. Test results are to be used in conjunction with information obtained from patient's clinical evaluation and other diagnostic procedures.

Add. Information: NA

CPT Code: 87449

LEISHMANIASIS - See "Parasite Serology"

LEPTOSPIROSIS CULTURE

Synonyms: NA
Test Laboratory: CDC Leptospira, 404-639-3905
Days Test Performed: Referred to CDC
Request Form: CDC Form
Special Instructions: Blood specimens should be collected during the first week of symptoms. After the first week of symptoms, collect a mid-stream, clean catch urine specimen. Five (5) tubes of PLM media should be requested from CDC prior to sample collection.
Specimen & Volume: 1 ml of heparinized blood or clean catch urine; Collect urine in clean container; Inoculate immediately; put two (2) drops of blood or urine in each tube of medium; Avoid agitation of the blood sample because free hemoglobin kills Leptospira
Container: Screw capped tubes of PLM media
Storage/Shipping Temperature: Store and ship at room temperature.
Shipping Description: See **Packing and Shipping Instructions, Section IV**
Rejection Criteria, specific: Blood specimen collected after first week of illness; specimen not inoculated into PLM media prior to transport. For universal rejections, See **Section I**
Methodology: Conventional culture
Add. Information: Serology test is more sensitive and has a shorter turnaround time.
CPT Code: Blood culture 87040; Urine culture 87088; Identification 87077

LISTERIA SPECIES

Synonyms: NA
Test Laboratory: Clinical Microbiology 803-896-0805
Days Test Performed: Monday – Friday.
Request Form: DHEC 1335, Test #511 (Organism for ID-aerobic/referred isolate)
Special Instructions: None
Specimen and Volume: Pure bacterial isolate on an agar slant that will support the growth of the isolate.
Container: Screw-capped tube containing agar slant that will support growth of isolate
Storage/Shipping Temperature: Store and ship at room temperature.
Shipping Description: See **Packing and Shipping Instructions in Section IV**. May use state courier for overnight delivery.
Rejection Criteria, specific: Culture non-viable; culture mixed. For universal rejections, See **Section I**
Methodology: VITEK MS, Conventional culture methods and biochemical analysis.
Additional Information: NA
CPT Code: Identification 87077

LYMPHOCYTE SUBSET

Synonyms: CD4; T4 lymphocytes
Test Laboratory: Clinical, Hematology unit, 803-896-0890
Days Test Performed: Monday – Friday; Specimen must be delivered to the laboratory by 1 PM

LYMPHOCYTE SUBSET (Continued)

on Fridays and any day prior to a recognized state-celebrated holiday.

Request Form: DHEC 1332, Test #780

Special Instructions: Specimen must be less than 24 hours old when tested by laboratory; Specimen must be delivered to the laboratory by 1 PM on Fridays and any day prior to a recognized state-celebrated holiday.

Specimen &Volume: 5-7 ml EDTA anticoagulated whole blood mix well but gently

Container: Lavender top (EDTA) vacuum tube See **Venipuncture Procedure, Section III**, if needed.

Storage/Shipping Temperature: Store and ship at room temperature. **Do not refrigerate.**

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimen more than 24 hours old upon arrival; specimen clotted; Specimen received cold or frozen. For universal rejections, See **Section I**

Methodology: Laser Flow cytometry

Add. Information: Used To evaluate HIV status

Reference value: CD4 cells 34-59%, CD4/CD8 ratio 0.9-3.1, results highly variable during progression of disease NOTE: Lymphocyte subset includes CBC results.

CPT Code: CD4/CD8 profile 86360; CBC 85025

MALARIA ANTIGEN TEST (BINAXNOW)

Synonyms: Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, Plasmodium malariae

Test Laboratory: Special Pathogens, 803-896-0777, 803-896-0773

Days Test Performed: As needed

Request Form: 1335, Test #521; Suspect agent "malaria"

Special Instructions: This organism has been designated as a Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777, 803-767-8118, or 803-896-0773. Specimen must be pre-approved by Special Pathogens department prior to testing.

Specimen & Volume: 3-5 mL EDTA and thin and thick pretreatment slides – See "Malaria Smear" (below).

Container: plastic EDTA tube

Storage/Shipping Temperature: EDTA tube should be sent at 2-8°C.

Shipping Description: Call Special Pathogens lab for further instructions

Rejection Criteria, specific: Call Special Pathogens lab for further instructions

Methodology: Antigen binding test

Add. Information: The antigen test is performed in the Special Pathogens laboratory. This is not a confirmatory test. Smears must be sent along with an EDTA tube per "Malaria Smear". For confirmation of smears, the Special Pathogens Department will take pictures of the smears and send them to DPDx at CDC for confirmation. Results from the test are not released independently. The BinaxNow results will be released with the DPDx smear results from CDC.

CPT Code: NA

MALARIA SMEAR

Synonyms: Giemsa stain; Blood parasite

Test Laboratory: Testing is no longer performed at the SC DHEC Public Health Laboratory. The malaria and diagnostic parasitology laboratories at CDC since June 2012 will be offering malaria species confirmation and malaria drug resistance testing services for cases of malaria diagnosed and treated in the United States. These tests will be provided free of charge. Service will include PCR-confirmation of the species, identification of drug resistance mutations, and when possible, parasite culture for direct susceptibility testing.

Special Instructions: The CDC requests that you please send a pre-treatment whole blood sample (EDTA) to CDC along with the electronic specimen submission form. For form and instructions go to http://www.cdc.gov/malaria/features/ars.html.

Specimen & Volume: **Blood Smears**: Send stained or unstained pretreatment slides (if unstained, fix thin smears in methanol as soon as possible after making the smear). Place slides in protective shipping holders to prevent breakage. If you with the slides to be returned, please indicate that on the CDC Electronic Submission form. **Blood for PCR or culture**: Draw pretreatment whole blood in 3 or 5ml EDTA or ACD blood tubes. **Serum for serology**: Draw 3 to 5ml blood in a clot or serum separator tube. Centrifuge and transfer serum into a shipping vial.

Container: EDTA Tube or ACD blood tubes and Slides

Storage/Shipping Temperature: For whole blood specimens<72 hours old, ship on cold packs as a "Clinical Specimen" by overnight carrier. For all other specimens, Store and ship at room temperature as a "Clinical Specimen" by overnight carrier.
All specimens should be shipped to CDC ATTN: DASH/Unit 52, 1600 Clinton Road, Atlanta, GA 30333.

Shipping Description: Ship Monday-Friday delivery ONLY. Packages cannot be accepted on weekends or on federal holidays. If you have questions about submitting specimens, contact DPDx at dpdx@cdc.gov or call 404-718-4110. Send the pre-treatment whole blood sample (EDTA) to CDC along with the electronic specimen submission form.
The specimen submission form and the instructions for shipping specimens can be found on this website: http://www.cdc.gov/malaria/features/ars.html. Specimens may be shipped overnight by the submitting facility.

Rejection Criteria, specific: Smears made from EDTA blood> 1 hour old; blood smears > 3 days old; For universal rejections, See **Section I**

Methodology: Microscopic examination of Giemsa stained smear

Add. Information: Used to detect blood parasites such as**:** malaria, microfilaria
Health care providers needing assistance with diagnosis or management of suspected cases of malaria should call the CDC Malaria Hotline: 770-488-7788 or 855-856-4713 toll-free (M-F, 9am-5pm, Eastern time). Emergency consultation after hours, call 770-488-7100 and request to speak with a CDC Malaria Branch clinician.

CPT Code: 87207

MCADD (Medium chain Acyl Co-A Dehydrogenase Deficiency) - See "Newborn Screening Panel"

MEASLES (RUBEOLA) RNA DETECTION BY REAL-TIME RT PCR

Synonyms: Measles (rubeola) PCR, RT-PCR, or rRT-PCR

Test Laboratory: Virology & Rabies, 803-896-0819

Days Test Performed: Monday-Friday, weekend and holiday testing approved on a case by case basis.

Request Form: DHEC 1335, Request "Measles PCR"

Special Instructions: All submissions require prior approval from Virology Section Supervisor (803-896-0819), the Microbiology Division Director (803-896-0870), or designee.

Specimen & Volume: Only throat swabs or nasopharyngeal swabs will be accepted. Ideally, samples should be collected within three days of symptom onset, however; samples collected up to fourteen days from symptom onset will be accepted. Use swabs with synthetic (polyester, nylon, etc) tips and aluminum or plastic shafts. DO NOT USE cotton, wood, or calcium alginate swabs. Place the swab in viral transport media for storage and shipment.

Container: A sterile, leak-proof, screw-capped tube containing viral transport media.

Storage/Shipping Temperature: Store in refrigerator; ship cold with cold packs. Specimen must be received at the Virology Section within 48 hours of collection. If transport is delayed, freeze at ≤ -70ºC and ship on dry ice.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Sample types other than throat or nasopharyngeal swabs; Swabs with cotton tips, calcium alginate tips, or wooden shafts; Specimens collected >14 days after symptom onset; Specimens shipped without transport media; Non-frozen specimens received >48 hours after collection. For universal rejections, See **Section I**

Methodology: Real-time RT-PCR

Add. Information: This test is used to detect the presence of measles (rubeola) virus nucleic acid (RNA). This test will not detect the German measles (rubella).

CPT Code: 87798

MEASLES SEROLOGY See "Rubeola Serology – IgM & IgG"

MHA-TP - See "TP-PA"

MITES - See "Scabies"

MUMPS RNA DETECTION BY REAL-TIME RT PCR

Synonyms: Mumps PCR, Mumps RT-PCR

Test Laboratory: Virology & Rabies, 803-896-0819

Days Test Performed: Monday – Friday, weekend and holiday testing approved on a case by case basis by the Microbiology Division Director only.

Request Form: DHEC 1335, Request "Mumps PCR"

Special Instructions: All submissions require prior approval from Virology Section Supervisor 803- 896-0819 or the Microbiology Division Director 803-896-0870, or designee. Only specimens

MUMPS RNA DETECTION BY REAL-TIME RT PCR (Continued)

submitted as apart of an epidemiological investigation will be accepted.

Specimen & Volume: One buccal swab collected within 14 days of symptom onset. Ideal collections occur within 3 days of symptom onset. Use swabs with polyester or nylon tips and aluminum or plastic shafts. DO NOT USE cotton, wood, or calcium alginate swabs. Place swab in viral transport media for storage and shipment. See **Collection Procedure for Mumps Virus (Buccal Swab), Section III**.

Container: A sterile, leak-proof, screw capped tube containing viral transport media.

Storage/Shipping Temperature: Store in refrigerator; ship with cold packs. Specimen must be received at the PUBLIC HEALTH LABORATORY within **48** hours of collection. If transport is delayed, freeze at -70ºC and ship on dry ice.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Cotton or alginate swabs or swabs with wooden shaft; Specimens collected greater than 14 days after symptom onset; Specimens shipped without transport media; non-frozen specimens received >**48** hours after collection. For universal rejections, See **Section I**

Methodology: Real-time reverse transcriptase polymerase chain reaction.

Add. Information: This test is used to detect the presence of mumps virus nucleic acid (RNA).

CPT Code: 87798

MUMPS VIRUS SEROLOGY IgG and IgM

Synonyms: Parotitis Epidemica Antibodies

Test Laboratory: Virology/Rabies, 803-896-0819

Days Test Performed: Mumps IgG once/week, Mumps IgM as needed

Request Form: DHEC 1332, Test #135 Mumps IgG (single specimen) Test #136 Mumps IgM

Special Instructions: None

Specimen & Volume: 2 ml whole clotted blood or 1 ml serum See **Venipuncture procedure, Section III**, if needed

Container: Red top vacuum tube or serum separator tube

Storage/Shipping Temperature: Store and ship at room temperature or 2-8ºC.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: None. For universal rejections, See **Section I**

Methodology: EIA for Mumps IgG, IFA for Mumps IgM

Add. Information: Mumps IgG Immune status reported as positive, negative or equivocal, Mumps IgM reported as positive or negative.

CPT Code: 86735

MYCOBACTERIAL CULTURE, BLOOD

Synonyms: TB, AFB

Test Laboratory: Mycobacteriology (TB), 803-896-0828

Days Test Performed: Monday-Friday

Request Form: DHEC 1335, Test #601

Special Instructions: Use Bactec 13A Vial (1) Clean septum of 13A vial with 70% alcohol; (2) Use good aseptic technique to cleanse arm; (3) Aseptically draw 4 to 5 ml blood and inject into 13A vial (4) Clean top of vial with 70% alcohol, cover top with tape and mail in mailer provided

MYCOBACTERIAL CULTURE, BLOOD (Continued)

Specimen & Volume: 4-5 ml whole Blood See **Venipuncture Procedure, Section III**, if needed.
Container: Bactec 13A Vial (call Lab for container, 896-0828)
Storage/Shipping Temperature: Store and ship at room temperature. Incubate at 37 º C if shipping is delayed over 24 hours.
Shipping Description: See **Packing and Shipping Instructions, Section IV**
Rejection Criteria, specific: Specimen >5 day old. For universal rejections, See **Section I**
Methodology: MGIT 9050 system, Gen-Probe
Add. Information: NA
CPT Code: Culture 87116; Identification–Gen-Probe 87149

MYCOBACTERIAL CULTURE, Other than Blood

Synonyms: AFB, TB
Test Laboratory: Mycobacteriology (TB), 803-896-0828
Days Test Performed: Monday – Friday
Request Form: DHEC 1335, Test #601
Special Instructions: None
Specimen & Volume: 5-10 ml sputum, and other body fluids; 10 ml urine or gastric washings, walnut sized portion of feces or 10 ml liquid stool See **Mycobacterium Culture Collection Procedure, Section III**
Container: Screw capped 50 ml polypropylene conical tube
Storage/Shipping Temperature: Store and ship sputum at room temperature. If shipping is delayed more than 24 hours, store in refrigerator. Store Urine in refrigerator and ship cold with cold packs.
Shipping Description: See **Packing and Shipping Instructions, Secion IV**
Rejection Criteria, specific: Specimen > 5 days old when received (Sputum and Urine). For universal rejections, See **Section I**
Methodology: Conventional culture methods, Gen-probe for ID
Add. Information: NA
CPT Code: Conc 87015; Culture 87116; Identification- Gen-Probe 87149

MYCOBACTERIAL CULTURE, REFERRED FOR IDENTIFICATION

Synonyms: AFB, TB
Test Laboratory: Mycobacteriology (TB), 803-896-0828
Days Test Performed: Monday - Friday
Request Form: DHEC 1335, Test #602
Special Instructions: None
Specimen & Volume: Send only pure culture with sufficient growth to perform test
Container: LJ slant preferred
Storage/Shipping Temperature: Store and ship at room temperature
Shipping Description: Infectious substance See **Packing and Shipping Instructions, Section**
Rejection Criteria, specific: Contaminated culture, non-viable organism. For universal rejections, **See Section I**

MYCOBACTERIAL CULTURE, REFERRED FOR IDENTIFICATION
(Continued)

Methodology: Gen-Probe
Add. Information: NA
CPT Code: GenProbe 87149

MYCOBACTERIA ANTIBIOTIC SUSCEPTIBILITY

Synonyms: Sensitivity Testing
Test Laboratory: Mycobacteriology (TB), 803-896-0828
Days Test Performed: Weekly on new TB isolates and by request on previously positive patients **(Sent to California State Lab for Testing)**
Request Form: DHEC 1335, Test #604
Special Instructions: Call Laboratory for drugs other than INH, Ethambutol, Rifampin, Streptomycin and Pyrazinamide.
Specimen & Volume: NA
Container: NA
Storage/Shipping Temperature: NA
Shipping Description: NA
Rejection Criteria, specific: None. For universal rejections, See **Section I**
Methodology: Versa Trek 87190; Conventional disk method 87184
Add. Information: NA
CPT Code: Versa Trek 87190; Conventional disk method 87184

NAEGLERIA FOWLERI

Synonym: NA
Test Laboratory: Testing is no longer performed at the SC DHEC Bureau of Laboratories. Special cases may be considered by the CDC Division of Parasitic Diseases. Contact the Clinical Microbiology at 803-896-0805 to arrange for testing.
Special Instructions: The CDC Division of Parasitic Diseases must be contacted prior to specimen submission. Specimens must be assigned a South Carolina testing number and submitted with a CDC DASH form (50.34).
Specimen &Volume: 1 ml CSF or small piece of tissue (brain, lung, corneal scrapings
Container: Sterile screw-capped tube containing small amount of Page's amoeba saline
Storage/Shipping Temperature: Store and ship at room temperature.
Shipping Description: After acquiring a South Carolina number and the CDC DASH form, specimens may be shipped overnight Monday – Thursday, avoid weekend deliveries by the submitting facility.
Rejection Criteria, specific: Specimen refrigerated or frozen, Formalin fixed specimens are not suitable for molecular studies For universal rejections, See **Section I**
Methodology: Conventional PCR, Real-Time PCR
Add. Information: NA
CPT Code: 87181

NEISSERIA MENINGITIDIS

Synonym: Bacterial meningitis

Test Laboratory: Clinical Microbiology 803-896-0805

Days Test Performed: Monday – Friday

Request Form: DHEC 1335, Test #511 (Organism for ID-aerobic/referred isolate).

Special Instructions: None.

Specimen and Volume: Pure bacterial isolate on an agar slant that will support the growth of the Isolate (chocolate agar is preferred).

Container: Screw-capped tube, containing agar slant that will support growth of isolate

Storage/Shipping Temperature: Store in a 35°C (CO2) incubator and ship at room temperature.

Shipping Description: See **Packing and Shipping Instructions in Section IV**. May use state courier for overnight delivery.

Rejection Criteria, specific: Culture non-viable; culture mixed. For universal rejections, see **Section I**

Methodology: VITEK MS, Conventional culture methods and biochemical analysis.

Additional Information: NA

CPT Code: Identification 87077

NEWBORN SCREENING PANEL

Synonyms: NA; Tests include: Amino Acid Profile (including PKU), Total Galactose (GAO) and galactose-1-phosphate uridyltransferase (GALT) enzymes, Thyroid Stimulating Hormone (TSH), 17-Hyroxy Progesterone (17-OHP), Hemoglobinopathies, Acylcarnitine Profile, Biotinidase, Immuno-Reactive Trypsinogen (IRT), Succinylacetone (SUAC), and T-cell Receptor Excision Circles (TREC), Cystic Fibrosis Mutation Analysis (CF-DNA) – performed as a 2nd tier/reflex test for IRT.

Test Section: Newborn Screening, 803-896-0874

Days Test Performed: Monday - Saturday

Request Form: DHEC # 1327, Newborn Screening Collection Form

Special Instructions: See **Capillary Blood Collection by Heel-stick, Section III**

Specimen & Volume: Dried Blood Spots collected on filter paper (DHEC form #1327); Fill each circle with 1 large drop of blood from a heel-stick

Container: Special Filter paper attached to request form and preaddressed mailing envelope

Storage/Shipping Temperature: Allow blood to dry 3-4 hrs before packing. Store and ship at room temperature within 24 hours of collection. Do **NOT** mail specimens in any type of plastic bag or packaging, or polymer-lined mailing envelope.

Shipping Description: See **Packing and Shipping Instructions, Section IV, "Shipping Newborn Screening Blood Spots"**

Rejection Criteria, specific: Specimens that are scratched, abraded, clotted, layered, contaminated, quantity insufficient; specimens that are older than 14 days; specimens from patients older than 1 year; specimens that are collected on an expired collection form; specimens that are shipped in a plastic bag, in a polymer-lined or bubble-wrap-lined envelope.

Methodology: TSH, 17-OHP, and IRT-Fluorimmuno assay (FIA); Hemoglobinopathies- High Performance Liquid Chromatography (HPLC) and IsoelectricFocusing (IEF); Amino Acid Profile, Acylcarnitines Profile and Succinylacetone (SUAC)-Tandem Mass Spectrometry; Biotinidase and GALT– Enzymatic and Fluorescense; Total Galactose-Fluorescence assay; TREC – PCR assay; CF-DNA- PCR and Flow Cytometry

NEWBORN SCREENING PANEL (Continued)

Add. Information: Interpretation: All results will be reported to the hospital, clinic, or institution and the attending physician (2 separate copies).

1. Amino Acid Profile:

The following amino acids are analyzed:

Valine
Leucine and Isoleucine
Methionine
Phenylalanine Citrulline
Tyrosine

2. Acylcarnitines Profile

This profile is run to detect abnormalities in fatty acid oxidation and organic acid metabolism. The following acylcarnitines are analyzed:

Free carnitine

C2 (Acetyl carnitine)

C3 (Propionyl carnitine)

C4 (Butyryl carnitine)

C5:1 (Tiglyl carnitine)

C5 (Isovaleryl carnitine)

C3DC (Malonyl carnitine) + C4-OH (3-Hydroxy-butyryl carnitine)
C6 (Hexanoly carnitine)

C4DC (Methylmalonyl carnitine) + C50H (3-Hydroxy-isovaleryl carnitine)

C8 (Octanoyl carnitine)

C10:2 (Decadienoyl carnitine)

C10:1 (Decenoyl carnitine)

C10 (Decanoyl carnitine)

C5DC(Glutaryl carnitine) + C6OH (3-Hydroxy-hexanoyl carnitine)

C12:1 (Dodecenoyl carnitine)

C6-DC (Adipyl carnitine)

C14:2 (Tetradecodienoyl carnitine)

C14:1 (Tetradecenoyl carnitine)

C14 (Myristoyl carnitine)

C16 (Palmitoyl carnitine)

C16-OH (3-hydroxyl Palmitoyl carnitine)

C18:2 (Linoleyl carnitine)

C18:1 (Oleyl carnitine)

C18 (Octadecanoyl carnitine)

C18:1-OH (3-hydroxyl Oleyl carnitine)

NEWBORN SCREENING PANEL (Continued)

CPT Codes: Amino Acid Profile 82139; TSH 84443; CAH 83498; Galactosemia 82760,82775; Hemoglobinapathies 83020; Acylcarnitines 82017; Biotinidase 82261; IRT for Cystic Fibrosis 83516; SUAC 82542; TREC for SCID 81479

NOROVIRUS DETECTION BY REAL TIME RT PCR

Synonyms: Norwalk Virus, Norovirus PCR

Test Laboratory: Virology & Rabies, 803-896-0819

Days Test Performed: Monday-Friday

Request Form: DHEC 1335, Test #114

Special Instructions: The availability of this test is restricted to epidemiological investigations. Approval for testing must be obtained and documented on the requisition prior to specimen submission. Please call 803-0819 to obtain approval.

Specimen & Volume: A peanut-sized or tablespoon volume of fresh diarrheal stool. Specimens collected within 48-72 hours of onset of symptoms are preferred. Specimens collected within 7 days of onset of symptoms will be accepted. Rectal swabs are not acceptable. Please batch submissions if possible.

Container: Sterile, screw capped, leak-proof, 50 ml conical tube or urine container

Storage/Shipping Temperature: Store in refrigerator and ship with cold packs.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimens placed in any type of media; Specimen not cold on arrival; Specimen more than 7 days old when received. For universal rejections, see **Section I**

Methodology: Real-time reverse transcriptase polymerase chain reaction (real-time RT-PCR)

Add. Information Used to detect the presence of Norovirus nucleic acid (RNA). Results are reported as negative or positive for the presence of genogroup I or genogroup II Norovirus.

CPT Code: Extraction 83890; Amplification 83898; Reverse transcriptase 83902

NOVEL CORONAVIRUS (MIDDLE EASTERN RESPIRATORY SYNDROME-MERS)

Synonyms: MERS

Test Laboratory: Special Pathogens, 803-896-0777/803-896-0773

Days Test Performed: As needed

Request Form: 1335, Test #521; Suspect agent "Novel Coronavirus" or "MERS"

Special Instructions: This organism has been designated as a Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777, 803-896-8118, or 803-896-0773. Specimen must be pre-approved by Special Pathogens department prior to testing.

Specimen & Volume: Nasopharyngeal and/or oropharyngeal swabs, sputum, lower respiratory aspirate/washes, serum; Volume depends on sample type.

Container: Various (Call Special Pathogens lab for further instructions)

Storage/Shipping Temperature: Call Special Pathogens lab for further instructions

Shipping Description: Call Special Pathogens lab for further instructions

Rejection Criteria, specific: Call Special Pathogens lab for further instructions

NOVEL CORONAVIRUS (MIDDLE EASTERN RESPIRATORY SYNDROME-MERS) (Continued)

Methodology: Real Time RT-PCR
Add. Information: NA
CPT Code: NA

PAP TEST, LIQUID-BASED MONOLAYER

Available only to DHEC county health department clinics

Synonyms: GYN Pap Test, Gynecologic Pap Test, Liquid-Based Pap Test; Monolayer Pap Test
Test Laboratory: Center of Disease Detection (CDD), 888-858-8663
Days Test Performed: Referred to CDD
Request form: CDD AFTIS
Special Instructions: Referred to CDD
Specimen & Volume: Referred to CDD
Container: Referred to CDD
Storage/Shipping Temperature: Referred to CDD
Shipping Description: Referred to CDD
Rejection Criteria, specific: Referred to CDD
Methodology: Referred to CDD
Add. Information: Referred to CDD
CPT Code: Monolayer Screen 88142; Physician's Interpretation 88141

PARAINFLUENZA VIRUS CULTURE- See "Respiratory Virus Culture"

PARASITE ID BY PCR

Parasite ID by PCR testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology.

Synonyms: Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia
Test Laboratory: Virology 803-896-0820
Days Test Performed: Monday – Friday **Note:** **For same day test results, must receive specimen by noon.**
Request Form: DHEC 1335, Test #410 other (specify)
Special Instructions: Call Clinical Microbiology
Specimen & Volume: Walnut sized portion of feces of 5-10 ml of liquid stool preserved in Cary-Blair stored in refrigerator
Container: Transport tube in Enteric Kit with Cary-Blair medium
Storage/Shipping Temperature: Ship on cold packs
Shipping Description: See **Packing and Shipping Instructions, Section IV**
Rejection Criteria, specific: Unpreserved stool and specimen perserved in PVA.
For universal rejections, See **Section I**
Methodology: FilmArray GI panel (PCR)
Add. Information: To detect the presence of *Cyclospora cayetanensis, Crytosporidium, Entamoeba histolytica, and Giardia lamblia*

PARASITE ID BY PCR (Continued)

Parasite ID by PCR testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology.

CPT Code: 87507

PARASITE SEROLOGY

Synonyms: NA; Test include: Chagas disease, cysticercosis, echinococcosis, leishmaniasis, malaria, schistosomiasis, trichinosis, visceral larva migrans (Toxocara)
Toxoplasmosis; For additional information call 803-896-0805.

Test Laboratory: Referred to Centers for Disease Control and Prevention (CDC) for testing

Days Test Performed: NA

Request Form: CDC Specimen Referral Form 50.34 Rev. 9-2002; Requesting laboratories must have a state public health number to include on this form. Please call 803-896-0805 to obtain number.

Special Instructions: None

Specimen & Volume: 2 ml Whole clotted blood or serum

Container: Red top vacuum tube See **Venipuncture Procedure, Section III**, if needed.

Storage/Shipping Temperature: NA

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: None. For universal rejections, See **Section I**

Methodology: NA

Add. Information: NA

CPT Code: NA

PKU - See "Newborn Screening Panel"

POLIOMYELITIS - See "Enterovirus culture"

QuantiFERON-TB Gold Plus (QFT)

Synonyms: QFT

Test Laboratory: Virology & Rabies, 803-896-0819/803-896-0820

Days Test Performed: Monday-Friday, weekend testing available with prior approval by Supervisor or Division Director.

Request Form: DHEC 1335, Test #605

Special Instructions: If specimens are incubated at regional incubation sites, the incubation start and end times must be included on the DHEC 1335. If the specimens will not be incubated at the regional sites, specimens must be received at the Virology laboratory within 16 hours of collection.

Specimen & Volume: Whole blood, 1mL in each tube. See **Ordering Supplies and Specimen Collection, Section III**

Container: Four (4) QuantiFERON-TB Gold Plus tubes – Nil antigen (Grey cap), TB 1 antigen (Green cap), TB 2 antigen (Yellow cap), Mitogen (Purple cap)

Storage/Shipping Temperature: Store at room temperature (17-25°C) prior to and after incubation. Ship room temperature via state courier in designated QFT shipper.

Shipping Description: Send to the attention of the Virology & Rabies laboratory in designated QFT shipper. See **Packing and Shipping Instructions, Section IV**

QuantiFERON-TB Gold Plus (QFT) (Continued)

Rejection Criteria: Specimen volume insufficient or overfilled, incubation performed incorrectly. For universal rejections, See **Section I**

Methodology: Detection of interferon-γ by ELISA

Additional Information: Additional shippers will be supplied upon request.

CPT Code: 86480

RABIES EXAMINATION

NOTE: The Public Health Laboratory is the only laboratory in S.C. which performs tests for rabies in animals. Human testing only performed at CDC with prior approval. Call Virology/Rabies before sending to obtain proper documentation, 803-896-0819/803-896-0820

Synonyms: NA

Test Laboratory: - Virology/Rabies, 803-896-0819

Days Test Performed: Monday- Friday only; Weekend and holiday only with notification and emergency testing criteria being met, specifically: (a) An unprovoked wild animal bite to a human, such as bites from a raccoon fox, skunk, bobcat, coyote, etc.; or (b) A bat when there is an obvious bat bite, or if individuals awaken and find a bat in their room, or if there is a bat in a room with an unattended child or near a mentally impaired or intoxicated person.

Request Form: DHEC 1308, Test #260

Special Instructions: Contact the local county health department for information on specimen collection and shipping instructions. **Confirmation is a postmortem procedure**; because standard procedure currently requires the examination of brain tissue, the suspect animal must either be sacrificed or have died before the examination can be performed. All county health departments maintain containers appropriate for shipping specimens for examination, information on the management of animals suspected of being rabid, and to obtain vaccine for persons exposed to a rabid animal after consultation with the state epidemiologist.

Specimen & Volume: Brain tissue

Container: Ship whole animal head. Heads are **only** submitted by DHEC Rabies Control Staff.

Storage/Shipping Temperature: Keep cold; See special instructions above.

Shipping Description: See special instructions above.

Rejection Criteria, specific: No brain tissue or tissue decomposed or grossly contaminated. For universal rejections, See **Section I**

Methodology: Fluorescent Antibody **(**FA)

Add. Information: Reported as positive or negative. All positive reports are called directly to the county health department, or after regular working hours, to the county environmentalist who submitted the specimen.

CPT Code: NA

RESPIRATORY PANEL 2 by FilmArray (PCR)

Respiratory Panel 2 by FilmArray testing is only available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology.

Synonyms: NA

Test Laboratory: Virology/Rabies, 803-896-0819

Days Test Performed: Monday - Friday

Request Form: DHEC 1335, Request FilmArray RP2 Panel

Special Instructions: Call Virology & Rabies Lab at 803-896-0819

RESPIRATORY PANEL 2 by FilmArray (PCR) (Continued)

Respiratory Panel 2 by FilmArray testing is only available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology.

Specimen & Volume: Nasopharyngeal Swab in Viral Transport Media. See **Viral Culture/Respiratory Culture/Herpes Culture Collection Procedure, Section III**

Container: Screw capped tube of viral transport media (Available upon request)

Storage/Shipping Temperature: Store in refrigerator. Ship with cold packs. If shipping is delayed more than 48 hours, freeze at -70°C and ship on dry ice.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimen type other than nasopharyngeal swab; Use of calcium alginate swab, Specimen not cold on arrival. For universal rejections, See **Section I**

Methodology: Multiplex PCR that identifies: Adenovirus (AdV); Coronavirus (CoV) 229E, HKU1, NL63, OC43; Enterovirus (EV); Human Rhinovirus (HRV); Human Metapneumovirus (hMPV); Influenza A (Flu A) (subtypes H1, H1-2009, and H3); Influenza B (Flu B); Parainfluenza Virus 1 (PIV1); Parainfluenza Virus 2 (PIV2); Parainfluenza Virus 3 (PIV3); Parainfluenza Virus 4 (PIV4); Respiratory Syncytial Virus (RSV); Bordetella pertussis; Bordetella parapertussis; Chlamydophila pneumoniae; and Mycoplasma pneumoniae

Add. Information: NA

CPT Code: NA

RESPIRATORY SYNCYTIAL VIRUS - See " Respiratory Virus Culture"

RESPIRATORY VIRUS CULTURE

Synonyms: Battery of tests includes culture for Influenza A and B, Parainfluenza I, II, III, Adenovirus, Human Metapneumovirus (hMPV), and Respiratory Synctial (RSV) from a single specimen.

Test Laboratory: Virology/Rabies, 803-896-0819

Days Test Performed: Monday - Friday

Request Form: DHEC 1335, Test #271

Special Instructions: Use swab with polyester tip.

Specimen & Volume: Throat swab (polyester tip), NP, upper Respiratory or lower Respiratory specimens See **Viral Culture/Respiratory Culture/Herpes Culture Collection Procedure, Section III**

Container: Screw capped tube of viral transport media (Available upon request)

Storage/Shipping Temperature: Store in refrigerator. Ship cold with cold packs within 24-48 hours. If shipping is delayed more than 48 hours, freeze at -70°C and ship on dry ice.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimen not cold on arrival; calcium alginate swab used for collection. For universal rejections, See **Section I**

Methodology: Virus isolation; centrifuge enhanced (Shell Vial) technique

Add. Information: NA

CPT Code: Culture 87254; Identification 87253

RPR - See "Syphilis Serology (STS)"

RUBELLA SEROLOGY- IgG and IgM

Synonyms: German measles antibody, rubella immune screen, rubella IgG; and IgM
Test Laboratory: Virology/Rabies, 803-896-0819
Days Test Performed: IgG – once /week and IgM – Referred to CDC
Request Form: DHEC 1332 - Test #006 for IgM, Test #005 for IgG
Special Instruction: Call prior to sending specimen for IgM, 896-0819
Rubella IgG does not require calling
Specimen & Volume: 2 ml whole clotted blood, or 1 ml serum
Container: Red top vacuum tube See **Venipuncture Procedure, Section III**, if needed.
Storage/Shipping Temperature: Store and ship at room temperature.
Shipping Description: See **Packing and Shipping Instructions, Section IV**
Rejection Criteria, specific: None. For universal rejections, See **Section I**
Methodology: EIA
Add. Information: NA
CPT Code: 86762 each immunoglobulin

RUBEOLA VIRUS SEROLOGY-IMMUNE STATUS/DIAGNOSTIC

Synonyms: Measles IgG, Measles IgM
Test Laboratory: Virology/Rabies, 803-896-0819
Days Test Performed: IgG – Once/Week and IgM – As needed
Request Form: DHEC 1332 - Test #111 for IgM, Test #132 for IgG
Special Instruction: Call prior to sending specimen for IgM, 896-0819
Rubella IgG does not require calling
Specimen & Volume: 2 ml whole clotted blood, or 1 ml serum
Container: Red top vacuum tube See **Venipuncture Procedure, Section III**, if needed.
Storage/Shipping Temperature: Store and ship at room temperature.
Shipping Description: See **Packing and Shipping Instructions, Section IV**
Rejection Criteria, specific: None. For universal rejections, See **Section I**
Methodology: EIA
Add. Information: IgM: Used in diagnosis of measles and during possible outbreaks. IgM antibodies usually appear 3-5 days after onset of rash. IgG: Used to determine immune status of patient.
CPT Code: 86765

SALMONELLA - See "Enteric Pathogens Culture“

SALMONELLA TYPHI - See "Enteric Pathogens Culture“

SCABIES

Synonyms: Mites, Sarcoptes scabei
Test Laboratory: Entomology – Dr. Evans, 803-896-3802
Days Test Performed: Monday - Friday
Request Form: DHEC 1335, Test #410

SCABIES (Continued)

Special Instructions: Place skin scrapings in 1-2 drops of mineral oil on a glass slide and cover with a cover slip. Please notify Dr. Evans prior to submission.

Specimen & Volume: Skin scrapings from infected area See **Collection Procedure for Scabies, Section III**

Container: Cardboard slide mailer in biohazard bag

Storage/Shipping Temperature: Store and ship at room temperature.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Too much oil used (several drops is too much). For universal rejections, See **Section I**

Methodology: Microscopic examination

Add. Information: Detection of scabies

CPT Code: 87210

SCHISTOSOMIASIS SEROLOGY - See "Parasite Serology"

SHIGA-TOXIN TEST – See "*Esherichia coli* – shiga-toxin producing"

SHIGELLA - See "Enteric Pathogens Culture"

SICKLE CELL - See "Hemoglobin Electrophoresis"

SPOROTRICHOSIS SEROLOGY

Synonyms: NA

Test Laboratory: Referred to CDC Mycoses Immunodiagnostic, 404-639-3469

Days Test Performed: Referred to CDC

Request Form: CDC form

Special Instructions: None

Specimen & Volume: 5 ml Whole clotted blood or 2 ml serum

Container: Red top vacuum tube See **Venipuncture Procedure, Section III**, if needed

Storage/Shipping Temperature: Store and ship at room temperature.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: None. For universal rejections, See **Section I**

Methodology: NA

Add. Information: NA

CPT Code: NA

STAPHYLOCOCCUS

Synonyms: "Enteric Pathogen Culture" or "Aerobe referred for Identification" for VISA/VRSA confirmation, see "*Staphylococcus* (VISA/VRSA) isolates"

Test Laboratory: Clinical specimens and isolates - Clinical Microbiology 803-896-0805; Food specimens – Food Microbiology 803-896-0872; MRSA/VRSA isolates from suspected outbreaks – Molecular Microbiology 803-896-0826

Days Test Performed: Upon request.

STAPHYLOCOCCUS (Continued)

Request Form: DHEC 1335, Test #510 (Call Food Microbiology for Food Specimen Form information)

Special Instructions: None.

Specimen and Volume: Swabs – transport in medium that will support the growth of the organism. Referred Isolate – transport on an agar slant that will support growth of the isolate. Food – call the food microbiology laboratory before shipping food samples (803-896-0872).

Container: Screw-capped tube containing agar slant that will support growth of isolate

Storage/Shipping Temperature: Ship at room temperature.

Shipping Description: See **Packing and Shipping Instructions in Section IV**. May use state courier for overnight delivery.

Rejection Criteria, specific: Culture non-viable; culture mixed. For universal rejections, See **Section I**

Methodology: Conventional culture methods and biochemical analysis. VITEK MS, Pulsed Field Gel Electrophoresis for outbreak investigations.

Additional Information: NA

CPT Code: 87077

STAPHYLOCOCCUS (VISA/VRSA) ISOLATES

Synonyms: VISA/VRSA

Test Laboratory: Clinical Microbiology 803-896-0805 and the Centers for Disease Control.

Days Test Performed: Upon request.

Request Form: DHEC 1335, Test #510

Special Instructions: According to the CDC and the 2010 CLSI update, only isolates with a commercial instrument MIC or Etest > 6 need to be sent to a reference laboratory for confirmation. According to the CDC, results from the Vitek 2, MicroScan, Phoenix, or Etest are accurate and correlate with studies performed at the CDC. MIC values of 2, 3, and 4 are not uncommon.

Specimen and Volume: Pure bacterial isolate on an agar slant that will support the growth of the isolate (chocolate agar is preferred). Include both isolated colony and at least one original culture plate, as resistance can be lost over time and subbing out organism.

Container: Screw-capped tube containing agar slant that will support growth of isolate

Storage/Shipping Temperature: Ship at room temperature.

Shipping Description: See **Packing and Shipping Instructions in Section IV**. May use state courier for overnight delivery.

Rejection Criteria, specific: Culture non-viable; culture mixed. For universal rejections, See **Section I**

Methodology: Conventional culture methods and biochemical analysis.

Additional Information: NA

CPT Code: 87077

STREPTOCOCCUS (BETA HEMOLYTIC GROUP A)

Synonym: Group-A Strep, Streptococcus pyogenes

Test Laboratory: Clinical Microbiology 803-896-0805

Days Test Performed: Monday - Friday

STREPTOCOCCUS (BETA HEMOLYTIC GROUP A) (Continued)

Request Form: DHEC 1335, Test #510

Special Instructions: Testing only available with consultation for outbreak investigations. Please contact Clinical Microbiology, 803-896-0870

Specimen and Volume: One (1) Throat Swab

Container: Culturette tube with transport medium or Bacterial swab transport

Storage/Shipping Temperature: Store and ship at room temperature.

Shipping Description: See **Packing and Shipping Instructions in Section IV**. May use state courier for overnight delivery.

Rejection Criteria, specific: Inappropriate specimen transport device; specimen in transit more than 3 days. For universal rejections, See **Section I**

Methodology: Conventional culture methods. VITEK MS.

Additional Information: Submit organisms (Grp-A Bets Strep) from sterile body sites to be frozen

CPT Code: Identification 87081

STREPTOCOCCUS PNEUMONIAE

SC 2017 List of Reportable Conditions. Specimen submission to the Public Health Laboratory is required for Streptococcus pneumoniae, invasive cases < 5 years of age.

Synonyms: NA

Test Laboratory: Clinical Microbiology 803-896-0805

Days Test Performed: Monday – Friday (Shipped to Wisconsin State Laboratory of Hygiene for serotyping)

Request Form: DHEC 1335, Test #511

Special Instructions: Testing is for Invasive cases < 5 years of age ONLY

Container: Standard Shipper

Specimen and Volume: Send isolate on Chocolate or Blood slant.

Storage/Shipping Temperature: Store in 35° CO2 incubator and Ship at room temperature.

Shipping Description: May use state courier for overnight delivery

Rejection Criteria, specific: Patient age > 5 years old. For universal rejections, See **Section I**

Methodology: PCR

Additional Information: SC 2017 List of Reportable Conditions

CPT Code: Identification 87046

SUSCEPTIBILITY TESTING - See "Mycobacterial Susceptibility"

SYPHILIS SEROLOGY SCREEN

Synonyms: RPR, Non-Treponemal Antibody

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday - Friday

Request Form: DHEC 1332 Test #001 or Test #235,

Special Instructions: None

Specimen &Volume: 1 ml serum

SYPHILIS SEROLOGY SCREEN (Continued)

Container: Serum-separator tube or serum. (Red top vacuum tubes may **only be used if** the sample is sent in within 24 hours or centrifuged and serum is removed from the clot and put into a different container/tube.) See **Venipuncture procedure Section III**, if needed.

Storage/Shipping Temperature: Please keep the sample refrigerated after allowing 30-60 minutes to clot. If sample will not be received within 24 hours, refrigerate and ship on a cold pack. Specimen must arrive within 3 days of collection.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria: Plasma specimen; more than 24 hours old if it was not refrigerated and sent on a cold pack. . Grossly contaminated, grossly lipemic, excessively hemolyzed, or chylous. For universal rejections, see Section I

Methodology: RPR

Add. Information: Quantitation performed on positives

CPT Code: 86592

T4 LYMPHOCYTES - See "Lymphocyte Subset"

TB CULTURE - See "Mycobacterial Culture"

TOXOPLASMA SEROLOGY- See "Parasite Serology"

TP-PA SEROLOGY

Synonyms: MHA-TP

Test Laboratory: Diagnostic Serology, 803-896-0811

Days Test Performed: Twice weekly usually Monday and Thursday

Request Form: DHEC 1332 Test #002 and Test #004

Special Instructions: None

Specimen & Volume: 0.5 mL of serum See **Venipuncture Procedure, Section III**, if needed.

Container: Serum-separator tube or serum. (Red top vacuum tubes may **only be used if** the sample is sent in within 24 hours or centrifuged and serum is removed from the clot and put into a different container/tube.)

Storage/Shipping Temperature: Stable for 24 hours at room temperature. If the sample will not be received at the laboratory within 24 hours, refrigerate and ship cold. Sample must be received within 72 hours from the date of collection.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria: Plasma specimen; more than 24 hours old if it was not refrigerated and sent on a cold pack. Grossly contaminated, grossly lipemic, excessively hemolyzed, or chylous. For universal rejections, See **Section I**

Methodology: Particle Agglutination

Add. Information: Used to determine the stage of infection; Not a screening test; Reactive test is usually reactive for life (85% of cases)

CPT Code: 86780

TRACE HEAVY METALS, URINE

Synonyms: NA

Test Laboratory: Analytical Chemistry, 803-896-0886

Days Test Performed: as requested

TRACE HEAVY METALS, URINE (Continued)

Request Form: DHEC 1332, Test #885
Special Instructions: None
Specimen & Volume: Minimum 10mL urine.
Container: Plastic urine container
Storage/Shipping Temperature: Store and ship urine frozen on dry ice. Freeze urine specimen if shipping is delayed.
Shipping Description: See **Packaging and Shipping Instructions, Section IV.** For further instructions please contact Analytical Chemistry at 803-896-0886.
Rejection Criteria, Specific: Insufficient quantity (QNS). For universal rejections, See **Section I.**
Methodology: Inductively Coupled Plasma Mass Spectrometry
Add. Information: NA
CPT Code: NA

TREPONEMAL ANTIBODY SEROLOGY See "TP-PA"

TRICHINOSIS - See "Parasite Serology"

TUBERCULOSIS CULTURE - See "Mycobacterial Culture"

TULAREMIA SEROLOGY

Synonyms: NA
Test Laboratory: Referred to CDC
Days Test Performed: NA
Request Form: CDC Form
Special Instructions: Contact Special Pathogens, 803-896-0777
Specimen & Volume: 2 ml Whole blood or serum
Container: Red top vacuum tube See **Venipuncture Procedure, Section III**, if needed.
Storage/Shipping Temperature: Store and ship at room temperature.
Shipping Description: See **Packing and Shipping Instructions, Section IV**
Rejection Criteria, specific: None. For universal rejections, See **Section I**
Methodology: NA
Add. Information: Interpretation printed on CDC report
CPT Code: 86000

VARICELLA VIRUS CULTURE

Synonyms: Chickenpox
Test Laboratory: Virology/Rabies, 803-896-0819
Days Test Performed: Monday - Friday
Request Form: DHEC 1335, Test #270
Special Instructions: Write 'Varicella' in block on form for Agent/Organism/Virus Suspected.
Specimen & Volume: Vesicle fluid

VARICELLA VIRUS CULTURE (Continued)

Container: Screw capped tube of viral transport media (Available upon request)

Storage/Shipping Temperature: Store in refrigerator and ship cold with cold packs. Ship within 24 hours after collection.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimen more than 24 hours old when received; Specimen not cold on arrival. For universal rejections, See **Section I**

Methodology: Cell culture

Add. Information: **NA**

CPT Code: Culture 87252; Identification 87253

VARICELLA VIRUS SEROLOGY

Synonyms: Chickenpox, Varicella-Zoster Virus Antibodies

Test Laboratory: Virology/Rabies, 803-896-0819

Days Test Performed: Once/Week

Request Form: DHEC 1332, Test #110 Varicella IgG for Immune Status

Special Instructions: NA

Specimen & Volume: 5 ml. whole blood or 2 ml serum; Single specimen for immune status, See **Venipuncture Procedure, Section III**, if needed.

Container: Red top vacuum tube

Storage /Shipping Temperature: Store and ship at room temperature.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: None. For universal rejections, See **Section I**

Methodology: EIA

Add. Information: Interpretation: Immune status**:** Positive, negative or equivocal

CPT Code: 86787

VARIOLA

Synonyms: Small Pox

Test Laboratory: Special Pathogens, 803-896-0777

Days Test Performed: As needed

Request Form: 1335, Test #521; Suspect agent "Small pox"

Special Instructions: This organism has been designated as a Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777, 803-767-8118, or 803-896-0773.

Specimen & Volume: Clinical samples and environmental samples (submitted by FBI)

Container: See Special Instructions Above

Storage/Shipping Temperature: See Special Instructions Above

Shipping Description: See Special Instructions Above

Rejection Criteria, specific: See Special Instructions Above

Methodology: Real Time PCR

Add. Information: NA

CPT Code: NA

VIBRIO - See "Enteric Pathogens Culture"

VIRAL CULTURE- See individual viral groups i.e. "Enterovirus or Respiratory Virus Culture", or individual virus, i.e. "Herpes" and "Varicella culture"

VIRAL ENTERIC CULTURE BY PCR

Viral Enteric culture testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology.

Synonyms: Adenovirus F 40/41, Astrovirus, and Sapovirus (note see individual virus groups for Rotavirus and Norovirus)

Test Laboratory: Clinical Microbiology, 803-896-0805

Days Test Performed: Monday - Friday

Request Form: DHEC 1335, Test #508 and (specify)

Special Instructions: Call Virology

Specimen & Volume: Walnut sized portion of feces or 5-10 ml of liquid stool
Infant specimens may be collected in a disposable diaper with plastic side facing inside.

Container: Transport tube in Enteric Kit with Cary-Blair medium

Storage/Shipping Temperature: Ship on cold packs

Shipping Description: See **Packing and Shipping Instructions, Section IV.**

Rejection Criteria, specific: Unpreserved stool and specimen preserved in PVA. For universal rejections, See **Section I**

Methodology: FilmArray GI panel (PCR)

Add. Information: To detect the presence of enteric viruses in a GI outbreak situation

CPT Code: 87507

VIRAL LOAD - See "HIV-1 PCR Quantitative (RNA)"

VISCERAL LARVA MIGRANS - See "Parasite Serology"

WEST NILE VIRUS SEROLOGY- IgM

Synonyms: Arbovirus serology

Test Laboratory: Virology/Rabies, 803-896-0819

Days Test Performed: As needed

Request Form: DHEC 1332, Test #117

Special Instructions: IgM on serum specimens; IgM only on CSF

Specimen & Volume: CSF, 2 ml serum or 4ml whole blood in red-top tube

Container: Sterile vacuum tube or appropriate tube for CSF collection

Storage/Shipping: **Temperature:** CSF must be shipped cold within 24 hours. After 24 hours ship frozen on dry ice.; Serum may be shipped cold or at room temperature.

Shipping Description: See **Packing and Shipping Instructions, Section IV**

Rejection Criteria, specific: Specimen taken too early. For universal rejections, See **Section I**

Methodology: EIA

Add. Information: Positive results will be referred to CDC for additional testing.

CPT Code: IgM 86788

WHOOPING COUGH - See "*Bordetella pertussis"*

YERSINIA ENTERCOLITICA

Yersinia testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology.

Synonyms: NA

Test Laboratory: Clinical Microbiology 803-896-0805

Days Test Performed: Monday – Friday

Request Form: DHEC 1335, Test #508 for identification from stool. Test #511 for isolate speciation.

Special Instructions: NA

Container: Screw-capped tube containing Cary Blair transport medium. Submit referred isolate on agar slant in a screw capped tube.

Specimen and Volume: Walnut sized portion of feces or 5-10 ml of liquid stool. Infant specimens may be collected in a disposable diaper with outside facing in. Submit referred isolate on agar slant in a screw capped tube.

Storage/Shipping: **Temperature:** Store and ship stool preserved in Cary-Blair media at room temperature for arrival at the laboratory within 48 hours. Ship raw stool on cold packs for arrival at the laboratory within 24 hours. Ship slants at room temperature.

Shipping Description: See **Packing and Shipping Instructions in Section IV**. May use state courier for overnight delivery.

Rejection Criteria, specific: Quantity insufficient; specimen too old; improper transport media or conditions. For universal rejections, See **Section I**

Methodology: VITEK MS, Conventional culture methods and biochemical analysis.

Additional Information: NA

CPT Code: Identification 87046

YERSINIA PESTIS

Synonyms: Plague

Test Laboratory: Special Pathogens, 803-896-0777

Days Test Performed: As needed

Request Form: 1335, Test #520 or 521; Suspect agent "Yersinia pestis"

Special Instructions: This organism has been designated as a Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777, 803-767-8118, or 803-896-0773.

Specimen & Volume: Clinical samples, clinical isolates, and environmental samples (submitted by FBI)

Container: See Special Instructions Above

Storage/Shipping Temperature: See Special Instructions Above

Shipping Description: See Special Instructions Above

Rejection Criteria, specific: See Special Instructions Above

Methodology: A variety of sentinel and LRN methods are used to confirm or rule-out bacterial isolates.

Add. Information: NA

CPT Code: NA

ZIKA IgM

Synonyms: Zika IgM Serology
Test Laboratory: Virology/ Rabies, 803-896-0819
Days Test Performed: Weekly
Request Form: DHEC 1332, Test #120
Special Instructions: Paired specimens are NOT required. See Venipuncture Procedure, Section III
Specimen & Volume: 5 ml blood or 2 ml serum preferred; 0.5ml serum minimum
Container: Red top vacuum tube, Serum Separator
Storage/Shipping Temperature: Store and ship at 2-8°C
Shipping Description: See **Packing and Shipping Instructions, Section IV**
Rejection Criteria, specific: None. For universal rejections, See **Section I**
Methodology: IgM Capture ELISA
CPT Codes: 86790

ZIKA VIRUS DETECTION BY REAL-TIME RT-PCR

Synonyms: Zika
Test Laboratory: Virology & Rabies, 803-896-0819
Days Test Performed: As needed
Request Form: DHEC 1335, Request "Trioplex RT-PCR"
Special Instructions: Paired specimens are NOT required. See **Venipuncture Procedure, Section III**; Urine collection: sterile screw-capped cup.
Specimen & Volume: 1-2 mL serum and 1-2 mL urine. Serum is required for testing.
Container: Serum Separator; Sterile, Screw-capped Cup (Urine)
Shipping Description: See **Packing and Shipping Instructions, Section IV**
Storage/Shipping Temperature: Store and ship at 2-8°C
Rejection Criteria, specific: None. For universal rejections, See **Section I**
Methodology: Trioplex Real-Time reverse transcriptase PCR (real-time RT-PCR)
Add. Information: Used to detect the presence of Zika nucleic acid (RNA). Results are reported as negative or positive.
CPT Code: 87798

SECTION III

ORDERING SUPPLIES
And
SPECIMEN COLLECTION

ORDERING SUPPLIES/FORMS/MAILING CONTAINERS

The Public Health Laboratory will provide request forms, kits, media and mailing containers for the collection and shipping of laboratory specimens. These supplies are provided free of charge. Please use them judiciously and use **ONLY** to send laboratory specimens to the Public Health Laboratory, SCDHEC, 8231 Parklane Road, Columbia, SC 29223. Supplies may be obtained by indicating the quantity required on **DHEC form 1323**, "Request for Laboratory Supplies". **Call 896-0913** to request these ordering forms or to request supplies, or mailing/shipping containers.

COLLECTION KITS

These kits contain collection materials, request form, an inside screw capped containment container with label, and a cardboard mailing container with a color coded mailing label attached. These are currently accepted by State and private couriers, and the US postal service. Each kit is to be used for only one specimen,

B. pertussis PCR kit	Insulated Shipper – Non Courier Customers
Enteric kit (for Bact. Culture)	Pink Label
Influenza kit	Insulated Shipper or Brown Box
Mycobacteriology (collection kit for TB)	Yellow Label

TRANSPORT MEDIUM

(Order request forms and shipping container separately.)

GC Culture medium
Pertussis transport medium (Regan-Lowe)
Viral Transport Media

OTHER SUPPLIES

Absorbent Packs
Biohazard Bags
Envelopes (for Newborn Screening and Hb electrophoresis blood spots)
GC/Chlamydia (for Antigen Detection) Unisex swab, vaginal swab, or urine collection kit
PPT Tubes for Viral Load
QuantiFERON-TB Gold Plus (QFT Plus) Tubes

MAILING/SHIPPING CONTAINERS

(Shipping infectious specimens by courier or US postal system)

Mailing containers Screw cap: No. 10 (2 ½" x 6"), No. 20 (3" x 6"), and No. 30 (4" x 6")
Mailing boxes: 4" x 4", 6" x 6", and 8" x 8"
Rabies Container
Shipping Container (for shipping infectious substances)
Hospitals and other clients using a commercial carrier must use special approved mailing containers These have been distributed and must be returned for re-use.

REQUEST FORMS

The request forms provided by the Public Health Laboratory are listed below. Forms marked with a + will be pre-addressed with your name, address and sender number. Since an over-supply cannot be returned to stock, please use discretion in the number you request. **DO NOT LOAN OR BORROW** preprinted forms to another client. The preprinted sender number determines where result reports are mailed. Forms are periodically revised. Please discontinue use of old forms once a revision has been made.
A separate DHEC form 1323 (Request for Laboratory Supplies) must be submitted for each location with a unique sender number.

Form #	Test (revision date)	Form color
1308	+Rabies	White
1323	Request for Lab Supplies (8/00)	Card stock/buff
1327	Newborn Screening (10/2016) **(check expiration date on form)**	White with green lettering
1332	+GC/ Chlamydia Screening	White
1332	+Hematology	White
1332	+ HIV Hepatitis /Syphilis Serology	White
1332	+Immunology	White
1332	+Lead Analysis	White
1332	+Lymphocyte Subset Panel	White
1332	+Serum Chemistry	White
1335	+Bacteriology	White
1335	+ Molecular	White
1335	+Mycobacteriology	White (Included in kit)
1335	+Parasitology	White
1335	+Virus Isolation/Herpes	White
1339	Hemoglobin Electrophoresis (5/2017)	Lt. Green

+Preaddressed

DHEC District laboratories forms:
These are available from Central Supply in the Sims/Aycock Building, 2600 Bull Street Columbia, SC 29201, (803) 898-3498.

SC DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
PUBLIC HEALTH LABORATORY
8231 Parklane Road Columbia, SC 29223
(803) 896-0800
CLIA # 42D0658606

Date Received
PHL Specimen Number

Patient's Name (Last)	(Suffix)	(First)	(MI)	Sex	Ethnicity	Race	Date of Birth MO DAY YR

Address	City	State	Zip Code	County of Residence	Miscellaneous

MCI Number (CHD CLIENTS ONLY)	Local ID	Clinic ID	Program Number	Country of Birth	Phone Number

Sender Number	Billing Number	Travel History

Sender Address

REASON FOR VISIT/TEST *(Check all that apply)*

__01 Volunteer/Medical
__02 Prev. Health - New
__03 Prev. Health - Established
__04 Contact
__06 Other_____
__08 Follow-Up
__09 Prev. Health - Brief
__10 Special Project
__11 Contact-HIV Positive
__12 Contact-Syphilis
__13 Referred -Self
__14 Referred-Other _____
__15 Workplace Exposure
__16 Diagnosis
__17 Repeat Test/First Test ____
__18 Routine Screen
__19 Test of Cure
__24 Rapid HIV Test Positive
__26 Contact-Hepatitis A
__27 Contact-Hepatitis B
__28 Contact-Hepatitis C
__33 Premarital (State____)
__34 Contact-HIV / PT notified
__35 Contact-HIV/ HD/MD notified
__37 Rapid HCV Positive
__38 Rapid HCV Negative
__39 Referred by Drug Trtmnt Ctr
__40 Previous HIV Positive
__42 Self-Report (Date_____)
__43 Pregnancy Test
__44 Contact-Gonorrhea
__45 Contact-Chlamydia
__46 Fast Track Services
__47 Fast Track Ineligible

SPECIMEN INFORMATION

Collection Date MO DAY YR | Collection Time __:__ __AM __PM | Initial ( )

Specimen Type/Source
___Blood
__Acute __Convalescent
__07 Finger; Heel; Toe Stick
__61 Plasma
__02 Serum/Serum-Separator
__01 Whole
_41 Venipuncture*
_51 EDTA-Lavender/Purple
_62 Clotted
___03 CSF
*Blood Lead Samples ONLY

___Swab
_53 Cervical
_16 Urethral
_57 Vaginal
___17 Rectal
___13 Throat
___98 Unknown
___04 Urine
___99 Other

CHLAMYDIA TEST

Pregnancy Status ___Yes ___No ___Unknown
Symptoms ___Yes ___No ___Unknown
Risk ___New Partner ___Multiple Partner

RISK HISTORY (Circle all that apply)

Past 12 months:
Client: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 31 32 33
Partner: 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30

SEROLOGY TEST SYMPTOMS

Outbreak Number: Date of onset:_____

Fever (temp)	Duration	Rash (type)

Please circle all that apply

Conjunctivitis	Headache	Muscle Weakness	Pharyngitis
Constipation	Jaundice	Nuchal rigidity	Pneumonia
Cough	Lethargy	Paralysis	Rhinitis
Diarrhea	Myocarditis	Pericarditis	Vomiting

ORDERING PHYSICIAN, PROVIDER AND/OR NURSE:

SPECIAL INSTRUCTIONS and/or COMMENTS:

TEST REQUESTED

SERUM CHEMISTRY
Patient: ___Fasting ___Non-Fasting

___713 ALT/AST
___715 TB Panel

HEMATOLOGY
Ship at room temperature

___760 CBC Panel
___780 CD4 (T4 Count)
___Initial Test
___Repeat Test

TOXIC CHEMICALS
*Individual metals upon request
___882 Hg, Pb, Cd screen in blood
___852 Lead (Blood)
___885 Trace Heavy Metal Urine Screen (Includes As, Be, Cd, Ba, Tl, Pb, U)*

VIROLOGY

___118 Chikungunya IgM
___119 Dengue IgM
___135 Mumps IgG
___136 Mumps IgM
___005 Rubella IgG
___006 Rubella IgM
___132 Rubeola (Measles) IgG
___111 Rubeola Measles) IgM
___110 Varicella IgG
___117 West Nile IgM
___120 Zika IgM

GC/CT DETECTION

___504 Trichomonas vaginalis -rRNA
___505 GC –rRNA
___506 Chlamydia -rRNA
___507 GC and Chlamydia –rRNA
___514GC/Chlamydia/Trich. vaginalis- rRNA

PHL USE ONLY

SEROLOGY

___019 Hepatitis A, IgG
___020 Hepatitis A, IgM
___226 Hepatitis B Anti-Core
___220 Hepatitis B Core IgM Antibody
___223 Hepatitis B Diagnostic Profile
___222 Hepatitis B Immune Status/Post Imm.
___228 Hepatitis B Surface Antibody
___225 Hepatitis B Surface Antigen
___224 Hepatitis C Antibody (HCV)
___227 Hepatitis C RNA
___230 HIV-1/HIV-2
___235 HIV-1/HIV-2 & RPR
___234 HIV-1/2 & Geenius
___231 HIV-1 Quant. RNA
___001 Syphilis RPR
___004 Syphilis-if RPR Pos do TP-PA
___002 TP-PA
___ _____
___ _____

DHEC 1332 (Revised 4/2018)

INSTRUCTIONS FOR COMPLETING REQUEST FORM

(May use printed patient lab label)

1. Enter patient name.
2. Write M = Male; F = Female or TX = Transgender M2F (Male to Female); or TY = Transgender F2M (Female to Male) in Sex box.
3. Enter ethnicity as follows: H = Hispanic/Latino, N = Non-Hispanic/Latino and U = Unknown
4. Enter race as follows: A = Asian; B = Black/African American; W= White; I = American Indian/Alaskan Native; P = Native Hawaiian/Other Pacific Islander; O= Other; U = Unknown/Unclassified
5. Enter date of birth (month, day and year. Example: Enter 03/06/1960 for the birthday March 6, 1960.)
6. Enter the patient address and five-digit zip code.
7. Enter county of residence and the 10-digit telephone number.
8. Fill in patient MCI ID number (DHEC Clients only).
9. Enter local and clinic ID if applicable. (Private clients must provide a clinic ID)
10. Enter Program number.
11. Enter Country of Birth.
12. Enter billing number if billing number is different from sender number
13. Enter Country of Birth.
14. Enter Travel History.
15. Enter the date and time of collection and initial.
16. Check type/source of specimen.
17. Enter Ordering Physician, Provider and/or Nurse if applicable. **Note: Please print.**
18. In the Reason for Visit/Test box, check all that apply.
19. Chlamydia test: Check pregnancy status, risk, and symptom.
20. Use the codes below to identify client and partner Risk Factors during the **PAST 12 MONTHS**. (Circle all that apply)

CLIENT RISK	**1.** Sex w/Female (F) **2.** Sex w/Male (M) **3.** Sex w/Transgender (T) **4.** Injection Drug Use (IDU) **5.** Used non-injectable drug or alcohol anytime during past 12-months **Received drugs/money in exchange for sex with a:** **6.** F/partner **7.** M/partner **8.** T/partner **Had sex while high on drugs with a:** **9.** F/partner **10.** M/partner **11.** T/partner **12.** Child of HIV infected mother **13.** Refused **14.** Other **31.** Without Condom **32.** Oral Sex w/Female **33.** Oral sex w/Male
PARTNER RISK	**Client had sex with:** **15.** F/IDU **16.** F/HIV + **17.** F/of unknown status **18.** F/who exchanges sex for drugs/money **19.** F/who has transfusions/transplant recipient **20.** M/IDU **21.** M/HIV + **22.** M/who exchanges sex for drugs/money **23.** Person who is a known MSM **(for female clients only)** **24.** M/of unknown status **25.** M/who has transfusions/transplant recipient **26.** T/IDU **27.** T/HIV + **28.** T/of unknown status **29.** T/who exchanges sex for drugs/money **30.** T/who has transfusions/transplant recipient

21. Enter the Outbreak Number.
22. Enter Date of Onset if applicable and circle all symptoms that apply.
23. Mark test requested.
24. Send top 2 copies of the form with the specimen(s) to the lab. **Please Retain Third Copy For Your Records.**

TB PANEL

Alkaline Phosphatase
ALT
AST
BUN
Creatinine
Glucose
T Bilirubin
Uric Acid
BUN/Creatinine Ratio* (Calculated values)

DHEC 1332 (4/2018)

SC DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
PUBLIC HEALTH LABORATORY
8231 Parklane Road Columbia, SC 29223
(803) 896-0800
CLIA # 42D0658606

Date Received
PHL Specimen Number

Patient's Name (Last)	(Suffix)	(First)	(MI)	Sex	Ethnicity	Race	Date of Birth MO DAY YR

Address	City	State	Zip Code	County of Residence	Phone Number

MCI Number (CHD CLIENTS ONLY)	Local ID	Clinic ID	Program Number	Country of Birth

Sender Number	Billing Number	Outbreak #

Sender Address

ORDERING PHYSICIAN, PROVIDER AND/OR NURSE:

Special Instructions and/or Comments:

SPECIMEN INFORMATION

Collection Date: MO / DAY / YR
Collection Time: ___AM ___PM
Initial: ( )

Date of Onset: ____/____/____

Agents/Organisms/or Virus suspected:

Clinical Diagnosis:

Specimen Type/Source

___ 07 BAL
___ 01 Blood
___ 28 Bronchial wash
___ 03 CSF
___ 14 Eye
___ 10 Feces
___ 34 Fluid _____ specify
___ 23 Genital _____ specify
___ 52 Nasopharyngeal Swab
___ 60 Sinus _____ specify
___ 65 Smear* _____ specify
___ 08 Sputum
__induced
__spontaneous
___ 13 Throat Swab
___ 12 Tissue/Biopsy _____ specify
___ 04 Urine
___ 32 Wound/Pus/Drainage
___ 33 Enteric Transport Media
___ 34 Test of Cure
___ 99 Other _____ specify
*Do not mark for TB samples

SYMPTOMS

__Asymptomatic
__Arthralgia/Myalgia
__Conjunctivitis
__Diarrhea
__Encephalitis
__Fever
__Meningitis
__Nausea/Vomiting
__Pleurodynia
__Rash _____ Type
__Respiratory
__Other:_____

TEST REQUESTED

CLINICAL MICROBIOLOGY (BACTERIOLOGY)

Was culture incubated before Transport: ___No ___Yes: __24 hrs. __48 hrs.

__501 GC Culture & ID
__502 Culture/Isolate for Shiga toxin producing E. coli
__503 Broth/Specimen for Shiga toxin producing E. coli
__508 Enteric Culture
__510 Non-Enteric Culture & ID
__511 Organism for ID- aerobic
__512 Legionella Urine Antigen Test
__513 BioFire FilmArray GI panel
__515 CRE/CRPA/CRAB
List organism_____
__Other _____ specify

VIROLOGY

SHIP ALL SPECIMENS FOR ISOLATION COLD

__114 Norovirus Detection by RT-PCR
__115 Bordetella Multiplex by RT-PCR
__121 GI Outbreak
__250 Herpes Culture (_____ Disease Active)
__270 Routine Viral Culture
__271 Influenza RT-PCR
__273 Mumps RT-PCR
__274 Measles RT-PCR
__275 CDC Trioplex RT-PCR
__276 BioFire Respiratory Panel
(outbreak investigations only)

MYCOBACTERIOLOGY

__601 Clinical Specimen for ID and smear
__602 Isolate for ID
__604 Drug Susceptibility
__Clinical Specimen
__Referred Isolate
__605 QuantiFeron TB-Gold
Incubation: start time _____
end time _____

Known TB case? Y N
R/O new TB case? Y N
Suspicious hx, s/sx? Y N
Current Rx? Y N

SPECIAL PATHOGENS

__520 Rule-out Testing: __Bacterial Isolate
__Clinical Specimen
Suspect Agent:_____
__521 Molecular Testing for Viral Agents:
__Influenza A: H5/H7 __MERS
__Ebola __Other
__522 Serological Testing:
__BMAT __Malaria

MOLECULAR

__120 PFGE Subtyping

__Other _____ Specify

CLINICAL MICROBIOLOGY (PARASITOLOGY)

__406 Cryptosporidium Antigen
__410 Other _____ Specify

PHL USE ONLY

DHEC 1335 (4/2018)

INSTRUCTIONS FOR COMPLETING REQUEST FORM
DHEC 1335

(May use printed patient lab label)

1. Enter patient name.
2. Write M = Male; F = Female or TX = Transgender M2F (Male to Female); or TY = F2M (Female to Male) in Sex box.
3. Enter ethnicity as follows: H = Hispanic/Latino and N = NonHispanic/Latino.
4. Enter race as follows: A = Asian
   B = Black/African American
   W= White
   I = American Indian/Alaskan Native
   P = Native Hawaiian/ Other Pacific Islander
   O= Other
   U = Unknown/Unclassified
5. Enter date of birth (month, day and year.) Example: enter 03/06/1960 for the birthday March 6, 1960.
6. Enter the patient address and five-digit zip code.
7. Enter county of residence and the 10-digit telephone number.
8. Fill in patient MCI ID number (DHEC Clients only).
9. Enter local and clinic ID if applicable. (Private clients must provide a clinic ID)
10. Enter Program number.
11. Enter Country of Birth.
12. Enter billing number if billing number is different from sender number.
13. Enter the Outbreak number.
14. Enter the date and time of collection and initial.
15. Check type/source of specimen.
16. Enter Ordering Physician, Provider and/or Nurse if applicable. **Note: Please print.**
17. Enter in the Special Instructions and/or comments where you vacated (travel history).
18. Enter Date of Onset if applicable.
19. List agents, organisms, or virus suspected.
20. Enter clinical diagnosis.
21. Check symptoms that apply.
22. Mark test requested.
23. Answer the four questions in Mycobacteriology Section.
24. Send top two copies of the form with the specimen(s) to the lab. PLEASE RETAIN THIRD COPY FOR YOUR RECORDS.

DHEC 1335 (4/2018)

BOL Specimen Number

SC DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
Public Health Laboratory
8231 Parklane Road Columbia, SC 29223
(803)896 -0800

Sample Master Number

8606

CLIA # 42D065

☐Cat ☐Dog ☐Bat ☐Fox ☐Raccoon ☐Skunk ☐Rodent (Specify) _____ ☐Other (Specify) _____	☐Wild ☐Pet ☐Stray Has the animal been vaccinated against rabies? ☐Yes ☐No ☐Unknown	Date of Death MO DAY YR Date of Vaccination MO DAY YR	
Sender Number	Abris Number	County Health Department Personnel	Office Phone Number / Cell Phone Number
Sender Address	**Address where the animal was found** Street: _____ City: County: _____ Zip Code: _____		

Was the animal shot in the head? ☐Yes ☐No Was the animal buried prior to shipment? ☐Yes ☐No
Was the animal frozen prior to shipment? ☐Yes ☐No

Reason for Testing: ☐Human Exposure ☐Domestic Animal Exposure ☐Other_____

Type of Exposure: ☐Bite ☐Scratch ☐Contact Saliva ☐Unknown ☐Other _____

Date of Exposure: **Exposure was** ☐Provoked ☐Unprovoked ☐NA

Name of Owner (Animal being tested)	Street	City/Zip Code	Telephone Number

HUMAN EXPOSURE (Complete the following)

Name of Person(s) Exposed	Street	City/Zip Code	Telephone Number

DOMESTIC ANIMAL EXPOSURE (Complete the following)

Type of Animal Exposed ☐Dog ☐Cat ☐Livestock (Specify) _____ ☐Other (Specify) _____	Name of Owner	
Street	City/Zip Code	Telephone Number

DO NOT WRITE BELOW THIS LINE – FOR LABORATORY USE ONLY

CONDITION OF BRAIN: ☐Acceptable ☐Unacceptable

LABORATORY RESULTS: ☐Positive ☐Negative
☐Unsatisfactory for testing, specimen decomposed or deteriorated
☐Unsatisfactory for testing, brain stem unavailable for testing

EXCEPTION: ☐Not tested. Brain deteriorated
☐Not tested. No brain present in skull.

Date Reported: _____

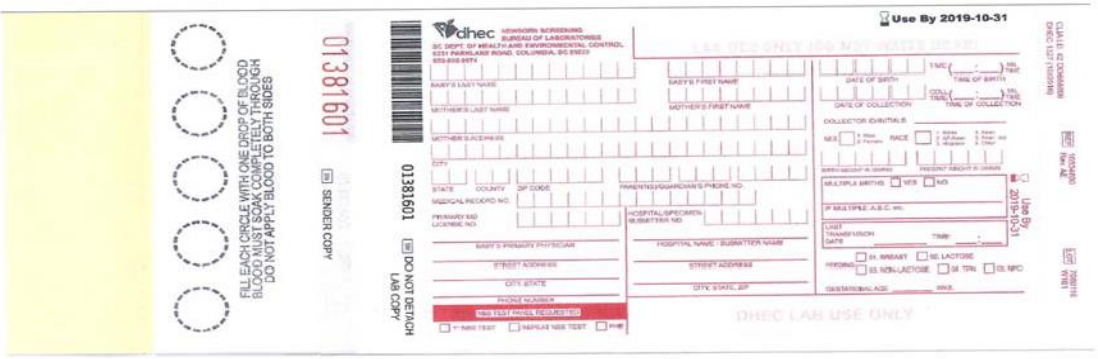
DHEC 1308 (Revised 06/17)

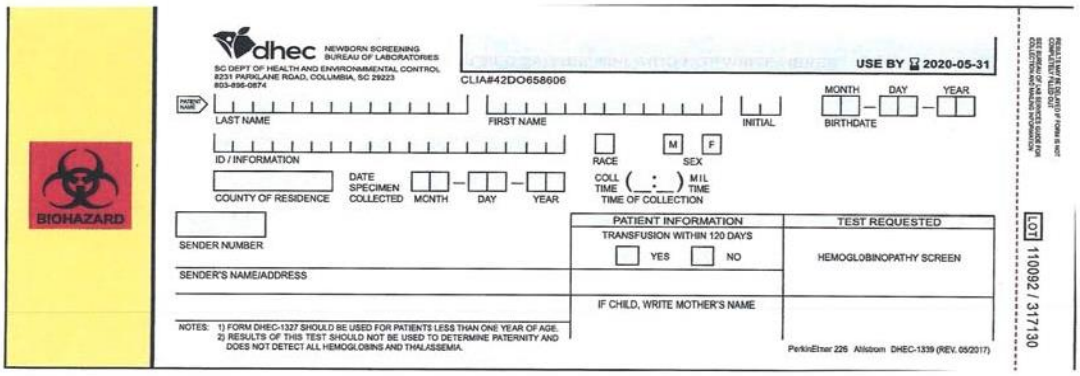
Personal information provided on this document is subject to public scrutiny or release.

Instruction for Completing Rabies Request Form

1. Check the appropriate box to identify the type of animal sent in for testing. If rodent or other is checked, specify the type of rodent (example: rat, mouse, etc) or type of other (example: opossum, horse, etc).
2. Check the appropriate box to identify the animal as wild, pet, or stray.
3. Enter the date of death.
4. Check box to indicate the animal's vaccination status. If inoculated against rabies, enter the vaccination date.
5. Enter sender number if not pre-printed on form.
6. Enter sender address if not pre-printed on form.
7. Enter Abris number used by the sender to identify the animal being tested for rabies.
8. Enter a contact person who will be responsible for receiving results.
9. Enter an office and home or cell phone number for the contact person.
10. Enter the address where the animal was found.
11. Check box to indicate if the animal was shot in the head, buried, or frozen priorto shipment.
12. Check the reason for testing and the type of exposure. Enter the date of exposure.
13. Check if the exposure was provoked or unprovoked.
14. Enter the name and address of the owner of the animal being tested. If the animal is stray or wild, leave blank.
15. If there was human exposure, give the name of the person(s) exposed, address, and phone number.
16. If there was pet exposure, check the type of pet or domestic animal exposed. Fill in the name of the owner of the animal exposed, the street address, city, zip code, and phone number.
17. Do not write in the "For Laboratory Use Only" box.
18. Send the top two copies to the form with the animal head. Retain the third copy for your records.

DHEC 1308 (Revised 10/16)


Use By 2019-10-31
dhec
NEWBORN SCREENING
BUREAU OF LABORATORIES
SC DEPT. OF HEALTH AND ENVIRONMENTAL CONTROL
8231 PARKLANE ROAD, COLUMBIA, SC 29223
803-896-0874
LAB USE ONLY (DO NOT WRITE IN BOX)
FILL EACH CIRCLE WITH ONE DROP OF BLOOD
BLOOD MUST SOAK COMPLETELY THROUGH
DO NOT APPLY BLOOD TO BOTH SIDES
01381601
SENDER COPY
01381601
DO NOT DETACH
LAB COPY
BABY'S LAST NAME
BABY'S FIRST NAME
MOTHER'S LAST NAME
MOTHER'S FIRST NAME
DATE OF BIRTH
TIME OF BIRTH
DATE OF COLLECTION
TIME OF COLLECTION
COLLECTOR IDENTIFIER
SEX
RACE
CITY
STATE
COUNTY
ZIP CODE
PARENT/GUARDIAN'S PHONE NO.
MEDICAL RECORD NO.
PRIMARY SSI
LICENSE NO.
HOSPITAL/SPECIMEN SUBMITTER NO.
BABY'S PRIMARY PHYSICIAN
HOSPITAL NAME / SUBMITTER NAME
STREET ADDRESS
CITY, STATE
PHONE NUMBER
STREET ADDRESS
CITY, STATE, ZIP
MULTIPLE BIRTHS
YES
NO
IF MULTIPLE, A,B,C, etc.
LAST TRANSFUSION DATE
TIME
FEEDING
GESTATIONAL AGE
WKS.
DHEC LAB USE ONLY
Use By 2019-10-31


BIOHAZARD
dhec
NEWBORN SCREENING
BUREAU OF LABORATORIES
SC DEPT OF HEALTH AND ENVIRONMENTAL CONTROL
8231 PARKLANE ROAD, COLUMBIA, SC 29223
803-896-0874
CLIA#42DO658606
USE BY 2020-05-31
PATIENT NAME
LAST NAME
FIRST NAME
INITIAL
MONTH
DAY
YEAR
BIRTHDATE
ID / INFORMATION
RACE
M
F
SEX
COUNTY OF RESIDENCE
DATE SPECIMEN COLLECTED
MONTH
DAY
YEAR
COLL TIME
MIL TIME
TIME OF COLLECTION
SENDER NUMBER
SENDER'S NAME/ADDRESS
PATIENT INFORMATION
TRANSFUSION WITHIN 120 DAYS
YES
NO
IF CHILD, WRITE MOTHER'S NAME
TEST REQUESTED
HEMOGLOBINOPATHY SCREEN
NOTES: 1) FORM DHEC-1327 SHOULD BE USED FOR PATIENTS LESS THAN ONE YEAR OF AGE.
2) RESULTS OF THIS TEST SHOULD NOT BE USED TO DETERMINE PATERNITY AND DOES NOT DETECT ALL HEMOGLOBINS AND THALASSEMIA.
PerkinElmer 226 Allsbrom DHEC-1339 (REV. 05/2017)
LOT 110092 / 317130

COUNTY CODES

Abbeville	01	Greenwood	24
Aiken	02	Hampton	25
Allendale	03	Horry	26
Anderson	04	Jasper	27
Bamberg	05	Kershaw	28
Barnwell	06	Lancaster	29
Beaufort	07	Laurens	30
Berkeley	08	Lee	31
Calhoun	09	Lexington	32
Charleston	10	Marion	33
Cherokee	11	Marlboro	34
Chester	12	McCormick	35
Chesterfield	13	Newberry	36
Clarendon	14	Oconee	37
Colleton	15	Orangeburg	38
Darlington	16	Pickens	39
Dillon	17	Richland	40
Dorchester	18	Saluda	41
Edgefield	19	Spartanburg	42
Fairfield	20	Sumter	43
Florence	21	Union	44
Georgetown	22	Williamsburg	45
Greenville	23	York	46

SENDER NUMBERS

Private Physician Usually consists of the S.C. Medical License number preceded by the letter M.

Group Practice A number preceded by the letter G will be assigned to group practices at their request. Use of the group number will insure that a single bill will be sent for tests submitted by all physicians in the practice. If you desire to be billed in this manner, please contact (803) 896-0800 for assignment of a group number. If each physician wishes to be billed separately, use the appropriate assigned sender number.

Hospital Consists of the hospital license number preceded by the letter H. If the test result is to be mailed directly to the patient's physician, use the physician's name, address and sender number in the appropriate spaces on the form and write the hospital sender number in the billing number space.

Private Laboratory A number assigned by the Public Health Laboratory. If not known, contact the lab at (803) 896-0800 for assignment.

DHEC County Health Depts. Consists of the assigned county code number preceded by a C.

BILLING NUMBERS

A billing number is only necessary if the test is to be billed to someone other than the sender.

PROGRAM NUMBERS

Used only when billing to a DHEC Program

0001 Immunization-VFC Operations
0002 Children with Special Health Care Needs (CSHCN)
0004 Family Planning
0005 Sickle Cell Program
0006 Maternal and Child Health (MCH)
0007 Cancer Control
0009 Tuberculosis Services - Outpatient
0011 Sexually Transmitted Diseases (STD)
0026 Adult Health
0027 Birth Defects (Metabolic Screening Program)
0031 Expanded & Integrated Human HIV Testing- Non-Clinical
0035 Expanded and Integrated HIV Testing for Populations-Clinical
0043 Environmental Health
0053 Newborn Metabolic Screening & Follow-Up
0055 Infant and Child Health Screening & Follow-Up
0059 WCS (Women & Children's Services)
0063 Employee Health Services
0070 Epidemiology - Disease Control
0072 HIV-AIDS Alcohol & Drug Abuse Project
0095 WIC
0111 HIV/AIDS
0202 Immunization Program
0301 BT CDC Public Health Emergency Preparedness

SPECIMEN COLLECTION PROCEDURES

Specimen Collection: Venipuncture Using the Vacuum System

Precaution: Wear non-latex gloves and liquid impervious laboratory coat or apron while collecting and preparing blood for shipment.

Supplies: see Clinical Formulary on the intranet for approved supplies

1. Vacuum tube system
2. Vacuum needle, 1 inch or 1 ½ inch; 18, 20, 21, 22, or 23 gauge
3. Disposable vacuum needle holder
4. Disposable tourniquet
5. 70% isopropyl alcohol or benzylkonium chloride pads
6. Sterile gauze pads (NO COTTON BALLS!)
7. Band-aids (optional)
8. Sharps disposal container (with stand or wall mounted)
9. Biohazard waste container

Personal Protective Equipment (PPE) Requirements:

1. Disposable gloves (required during collection)
2. Safety glasses (required if there is any chance of eye/mouth contamination during collection; strongly recommended if you wear contacts)
3. Liquid resistant/impervious lab coat or apron (required during collection)
4. Additional protection as recommended by OSHA and/or MSDS

Specimen Collection: You MUST have completed a DHEC Workshop and be rated proficient and competent BEFORE you can collect a venipuncture without direct supervision.

1. While putting on the appropriate PPE, explain the procedure to the patient and ask the patient to identify themselves or check a picture identification card.
    a. BEFORE putting on ANY PPE, wash hands with soap and water or use a hand sanitizer with at least 60% alcohol content.
    b. Order for putting on PPE: put eye protection on first (optional), then put on liquid resistant/impervious lab coat/apron, and then put on non-latex gloves.

2. Position the patient for taking blood from the antecubital vein, or the median cubital vein, or the cephalic vein.
    a. DIS can ONLY use one of these sites to collect venipuncture.
    b. MDs, APRNs, RNs, MTs, MLTs can use other sites on the arm or hand, if trained using standard Training Checklist and passed Competency Evaluation annually.

3. Apply disposable tourniquet to the arm just above the elbow and instruct the patient to make a fist; it is NOT necessary for the patient to "pump" their fist.
    a. Always palpate the vein with the disposable tourniquet BEFORE making a decision to puncture the vein.
    b. DO NOT leave the tourniquet on for >2 minutes during a venipuncture!

4. Select the best vein and cleanse the skin over the puncture site with 70% alcohol or benzylkonium chloride in ONE DIRECTION!
    a. **DO NOT** wipe back and forth with the 70 % alcohol/benzylkonium chloride.

b. Allow to dry without blowing on the site or fanning the site.
c. Once the site is dry, **DO NOT** palpate the vein with gloved finger; these are not sterile gloves.

5. Use sterile vacuum needle and attach (screwed onto) to a disposable adaptor.
   a. The vacuum collection tube may be inserted into the adaptor without danger of breaking the vacuum.
   b. **DO NOT** pierce the vacuum on the tube with the adapter needle.

6. "Fix" the vein selected for the venipuncture.
   a. Left thumb about an inch below where the needle is to enter.
   b. Press down on the arm and pull the skin toward the hand.
   c. The needle is to be in line with the vein.
   d. The needle is to be BEVEL SIDE UP!
   e. The needle is to be at approximately a 15 degree angle with the arm.
   f. You can adjust the angle depending on the depth of the vein.

7. Puncture the skin with a clean, smooth motion. BEVEL SIDE UP!
   a. **DO NOT** hesitate; this hurts.
   b. As the needle enters the vein, a little "give" will be felt.
   c. When inside the vein, grip the tube holder firmly and keep the holder steady.
   d. Press the vacuum tube onto the needle portion inside the holder.

8. While the needle is inside the vein, collect the required tubes of blood.
   a. Note: Collect blood in plain (red stopper) tubes before collecting blood in tubes with additives (e.g. EDTA)
   b. Note: DIS are ONLY allowed to collect a single tube per venipuncture.
   c. Mix tubes with additives by gently inverting 5-10 times to prevent clotting.
   d. **DO NOT** shake the tube(s)!
   e. Allow the red top tubes to stand in a test tube rack, upright, for at least 30 minutes to allow clotting before centrifugation.
   f. Note: some patients may take longer to clot, so allow extra time if patient is on maintenance doses of Coumadin and/or other platelet aggregate inhibitors.

9. Release tourniquet, withdraw needle from vein and apply pressure on venipuncture site with dry gauze.
   a. **DO NOT** cover the injection site with an alcohol sponge while withdrawing needle.
   b. **DO NOT** apply pressure on the venipuncture site with gauze if the needle is still in the arm!

10. Have patient apply pressure on the venipuncture site for 2-3 minutes to prevent leakage of blood under the skin and formation of a hematoma. When site no longer bleeds, a bandage may be applied if desired.
    a. Ask the patient to hold their arm straight up and lock their elbow.
    b. If the patient cannot do this, hold the arm straight up for them.

11. Label specimen tube (s) with proper patient identification information; if not already done when getting supplies together.
    a. Name of patient/client (first name and last name).
    b. MCI number or other unique identification number.
    c. Date collected, time collected and initials of person who collected specimen.
    d. Note: if you use a computer label, just add time and initials of person collecting specimen.

12. Complete ALL information on the test request/lab requisition form(s): DHEC 1332/1335.
    a. Name of patient/client (first name and last name).
    b. MCI number or other unique identification number.
    c. Date collected, time collected and initials of person who collected specimen.
    d. Test required
    e. Type of specimen
    f. Ordering physician, APRN, RN, DIS
    g. Test(s) requested
    h. Sender Address or Sender code number
    i. Any specimen instructions or other important information
    j. Note: if you use a computer label, just add time and initials of person collecting specimen.
    k. Note: if you use a computer label, be sure to place the computer label with all demographic information on copy 1, copy 2 and copy 3.
    l. You will send the original top copy of the DHEC 1332/1335 with the specimen(s)
    m. Retain the third copy for your files in the County Health laboratory.

13. Properly dispose of needles (in biohazard puncture proof sharps container) and other contaminated materials used during venipuncture.
    a. Place all blood soaked material in the contaminated waste bag (Biohazard).
    b. Place all sharps in the sharps container and DO NOT fill above 2/3!
    c. DO NOT place any non-contaminated waste in the sharps container or Biohazard waste!

14. Remove PPEs in this order:
    a. Remove contaminated gloves.
    b. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
    c. Remove any eye protection.
    d. Remove liquid impervious/resistant lab coat or apron.
    e. Wash hands with soap and water or with hand sanitizer with >60% alcohol.

15. BEFORE allowing the patient/client to leave, take the gauze off of the venipuncture site to ensure it has stopped bleeding.
    a. DO NOT wipe the area with gauze since this will initiate bleeding again (subcutaneous) and may cause a hematoma (bruise).
    b. DO NOT allow patient to get up from the chair, table, etc. without being physically at the side or in front of the patient/client: THIS IS A FALL PREVENTION MEASURE!

16. NOTE: DIS staff can ONLY draw one tube; no multi-draws or multiple tubes collected from the same venipuncture collection site.

17. No DIS staff can be trained and/or use a butterfly to collect a venipuncture.

Specimen Preparation:

1. Blood collected in a plain red stopper tube or in a serum separator tube (SST): allow the tube of blood to remain undisturbed in an upright position at room temperature for 20-30 minutes.
    a. When the specimen has clotted, DO NOT allow the serum to sit on the clot, whether collected in a red tube or SST tube, without separating through centrifugation; then store according to instructions in the Reference Laboratory manual for specimen collection and transport.
    b. Note: check manufacturer's package insert for maximum time blood can sit on clot BEFORE centrifugation, if using an SST (serum separator tube).

2. After a clot has formed, gently loosen the clot at the top; "rim" with a sterile applicator stick, if necessary.

3. Centrifuge tubes for 10-15 minutes.
   a. Since all centrifuges are calibrated by Instrumentation Department (Facilities Management Division, Public Health Laboratory), the time for most centrifugation needs will be on the instrument.
   b. CHECK OUT THE CALIBRATED TIME/SPEED ON YOUR CENTRIFUGE!

4. Remove the serum carefully with a sterile transfer pipette, and transfer to a clean sterile rubber- stoppered tube or to a screw-top, plastic vial/tube. Avoid transferring any red cells.

5. Label tube or plastic vial running up the length of the tube.
   a. **Do NOT** wrap the label around or "flag" the label by pressing ends together and extending from the tube.
   b. This includes ALL vacuum tubes for chemistry, hematology and serology; red top, SST, or purple (EDTA) top tubes would be the common ones.

6. Store tubes of labeled serum in a refrigerator until the specimens are ready to ship to the clinic laboratory or the Public Health Laboratory.

Special Procedural Notes:

1. If sending whole blood in a vacuum tube, omit steps 2 and 4 (see page III-6).

2. If using serum separator tubes (gel in the bottom of the tube, SST) omit steps 2 and 4 above. Be sure the gel forms a distinct barrier between serum and clot.

3. During the summer months, pack all SST specimens with a cold pack since the gel can possibly breakdown at temperatures experienced during the summer months. The breakdown of the gel allows the red blood cells to "leak" into the serum contaminating the specimen and possibly rendering the specimen unacceptable for testing.

4. Never use a gauge needle size smaller than a 23: this can cause hemolysis!

6. Always allow the blood to flow into a vacuum tube without adding additional pressure.

7. **DO NOT** take disposable tourniquet off until you have collected ALL of the tubes and the tubes are filled: when you take the tourniquet off once you are inside you run the risk of slow blood flow and/or short draws and/or insufficient blood volume.

8. For special considerations using a butterfly for a venipuncture, see the next procedure.

Specimen Collection: Venipuncture Using a Butterfly System

Precaution: Wear non-latex gloves and liquid impervious laboratory coat or apron while collecting and preparing blood for shipment.

Supplies: see Clinical Formulary on the intranet for approved supplies

1. Vacuum tube system
2. Butterfly needle: 21g, 22g, or 23g (NO SMALLER THAN 23G!)
3. Disposable vacuum needle holder
4. Disposable tourniquet
5. 70% isopropyl alcohol or benzylkonium chloride pads
6. Sterile gauze pads (NO COTTON BALLS!)
7. Band-aids (optional)
8. Sharps disposal container (with stand or wall mounted)
9. Biohazard waste container

Personal Protective Equipment (PPE) Requirements:

1. Disposable gloves (required during collection)
2. Safety glasses (required if there is any chance of eye/mouth contamination during collection; strongly recommended if you wear contacts)

3. Liquid resistant/impervious lab coat or apron (required during collection)
4. Additional protection as recommended by OSHA and/or MSDS

Specimen Collection: You MUST have completed a DHEC Workshop and be rated proficient and competent BEFORE you can collect a venipuncture without direct supervision. No DIS staff can be trained using this method.

Note: the use of a butterfly is to be used ONLY in special circumstances: elderly patients with non-patent veins; young children (less than 4 years old) or babies; patients with non-patent veins and the hand is the site of choice.

1. While putting on the appropriate PPE, explain the procedure to the patient and ask the patient to identify themselves or check a picture identification card.
   a. BEFORE putting on ANY PPE, wash hands with soap and water or use a hand sanitizer with at least 60% alcohol content.
   b. Order for putting on PPE: put eye protection on first (optional), then put on liquid resistant/impervious lab coat/apron, and then put on non-latex gloves.

2. Position the patient for taking blood from the antecubital vein, or the median cubital vein, or the cephalic vein: these are all on the arm.
   a. DIS can ONLY use one of these sites to collect venipuncture.
   b. MDs, APRNs, RNs, MTs, MLTs can use other sites on the arm or hand, if trained using standard Training Checklist and passed Competency Evaluation annually.
      1) Veins from the hand that can be used are: basilic veins (runs along the 5th digit, little finger).
      2) Veins from the hand that can be used are: metacarpal veins (runs along the 2nd or 4th digit, index/pointer finger and ring finger).
      3) Veins from the hand that can be used are: cephalic vein (runs along the side of wrist area or just above the thumb).

4) NO OTHER sites are to be used with the butterfly other than those listed in the venipuncture using the vacuum and the butterfly; no femoral, no temporal, no jugular, etc.

3. Apply disposable tourniquet to the arm just above the elbow, or on the forearm if using the hand, and instruct the patient to make a fist; it is NOT necessary for the patient to "pump" their fist.
   a. Always palpate the vein with the disposable tourniquet BEFORE making a decision to puncture the vein.
   b. DO NOT leave the tourniquet on for >2 minutes during a venipuncture!

4. Select the best vein and cleanse the skin over the puncture site with 70% alcohol or benzylkonium chloride in **ONE DIRECTION!**
   a. **DO NOT** wipe back and forth with the 70 % alcohol/benzylkonium chloride.
   b. Allow to dry without blowing on the site or fanning the site.
   c. Once the site is dry, **DO NOT** palpate the vein with gloved finger; these are not sterile gloves.

5. Use sterile butterfly needle and attach (screwed onto) to a disposable adaptor.
   a. If a butterfly is used with a syringe (5cc, 7cc or 10cc), collect the specimen following the same steps, except you will fill the vacuum tubes with the blood from the syringe.
   b. **DO NOT** put blood into the vacuum tubes by pressing the needle through the rubber septum; take the rubber septum off and gently add blood to the tube.
   c. The vacuum collection tube may be inserted into the adaptor without danger of breaking the vacuum.
   d. **DO NOT** pierce the vacuum on the tube with the adapter needle.

6. "Fix" the vein selected for the venipuncture.
   a. Left thumb about an inch below where the needle is to enter.
   b. Press down on the arm and pull the skin toward the hand.
   c. The needle is to be in line with the vein.
   d. The needle is to be BEVEL SIDE UP!
   e. The needle is to be at approximately a 15 degree angle with the arm.
   f. You can adjust the angle depending on the depth of the vein.

7. Puncture the skin with a clean, smooth motion. BEVEL SIDE UP!
   a. **DO NOT** hesitate; this hurts.
   b. As the needle enters the vein, a little "give" will be felt.
   c. When inside the vein, grip the tube holder firmly and keep the holder steady.
   d. Press the vacuum tube onto the needle portion inside the holder.

8. While the needle is inside the vein, collect the required tubes of blood.
   a. **Note: Collect blood in plain (red stopper) tubes before collecting blood in tubes with additives (e.g. EDTA**).
   b. Note: DIS is ONLY allowed to collect a single tube per venipuncture.
   c. Mix tubes with additives by gently inverting 5-10 times to prevent clotting.
   d. **DO NOT** shake the tube(s)!
   e. Allow the red top tubes to stand in a test tube rack, upright, for at least 30 minutes to allow clotting before centrifugation.
   f. Note: some patients may take longer to clot, so allow extra time if patient is on maintenance doses of Coumadin and/or other platelet aggregate inhibitors.

9. Release tourniquet, withdraw needle from vein and apply pressure on venipuncture site with dry gauze.

    a. **DO NOT** cover the injection site with an alcohol sponge while withdrawing needle.
    b. **DO NOT** apply pressure on the venipuncture site with gauze if the needle is still in the arm!

10. Have patient apply pressure on the venipuncture site for 2-3 minutes to prevent leakage of blood under the skin and formation of a hematoma. When site no longer bleeds, a bandage may be applied if desired.
    a. Ask the patient to hold their arm straight up and lock their elbow.
    b. If the patient cannot do this, hold the arm straight up for them.

11. Label specimen tube (s) with proper patient identification information; if not already done when getting supplies together.
    a. Name of patient/client (first name and last name).
    b. MCI number or other unique identification number.
    c. Date collected, time collected and initials of person who collected specimen.
    d. Note: if you use a computer label, just add time and initials of person collecting specimen.

12. Complete ALL information on the test request/lab requisition form(s): DHEC 1332/1335.
    a. Name of patient/client (first name and last name).
    b. MCI number or other unique identification number.
    c. Date collected, time collected and initials of person who collected specimen.
    d. Test required
    e. Type of specimen
    f. Ordering physician, APRN, RN, DIS
    g. Test(s) requested
    h. Sender Address or Sender code number
    i. Any specimen instructions or other important information
    j. Note: if you use a computer label, just add time and initials of person collecting specimen.
    k. Note: if you use a computer label, be sure to place the computer label with all demographic information on copy 1, copy 2 and copy 3.
    l. You will send the original top copy of the DHEC 1332/1335 with the specimen(s)
    m. Retain the third copy for your files in the County Health laboratory.

13. Properly dispose of needles (in biohazard puncture proof sharps container) and other contaminated materials used during venipuncture.
    a. Place all blood soaked material in the contaminated waste bag (Biohazard).
    b. Place all sharps in the sharps container and DO NOT fill above 2/3!
    c. **DO NOT** place any non-contaminated waste in the sharps container or Biohazard waste!

14. Remove PPEs in this order:
    a. Remove contaminated gloves.
    b. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
    c. Remove any eye protection.
    d. Remove liquid impervious/resistant lab coat or apron.
    e. Wash hands with soap and water or with hand sanitizer with >60% alcohol.

15. BEFORE allowing the patient/client to leave, take the gauze off of the venipuncture site to

ensure it has stopped bleeding.

a. **DO NOT** wipe the area with gauze since this will initiate bleeding again (subcutaneous) and may cause a hematoma (bruise).
b. **DO NOT** allow patient to get up from the chair, table, etc. without being physically at the side or in front of the patient/client: THIS IS A FALL PREVENTION MEASURE!

Specimen Preparation:

1. Blood collected in a plain red stopper tube or in a serum separator tube (SST): allow the tube of blood to remain undisturbed in an upright position at room temperature for 20-30 minutes.
   a. When the specimen has clotted, DO NOT allow the serum to sit on the clot, whether collected in a red tube or SST tube, without separating through centrifugation; then store according to instructions in the Reference Laboratory manual for specimen collection and transport.
   b. Note: check manufacturer's package insert for maximum time blood can sit on clot BEFORE centrifugation, if using an SST (serum separator tube).

2. After a clot has formed, gently loosen the clot at the top; "rim" with a sterile applicator stick, if necessary.

3. Centrifuge tubes for 10-15 minutes.
   a. Since all centrifuges are calibrated by Instrumentation Department (Facilities Management Division, Public Health Laboratory), the time for most centrifugation needs will be on the instrument.
   b. CHECK OUT THE CALIBRATED TIME/SPEED ON YOUR CENTRIFUGE!

4. Remove the serum carefully with a sterile transfer pipette, and transfer to a clean sterile rubber- stoppered tube or to a screw-top, plastic vial/tube. Avoid transferring any red cells.

6. Label tube or plastic vial running up the length of the tube.
   a. **Do NOT** wrap the label around or "flag" the label by pressing ends together and extending from the tube.
   b. This includes ALL vacuum tubes for chemistry, hematology and serology; red top, SST, or purple (EDTA) top tubes would be the common ones.

6. Store tubes of labeled serum in a refrigerator until the specimens are ready to ship to the clinic laboratory or the Public Health Laboratory.

Special Procedural Notes:

1. If sending whole blood in a vacuum tube, omit steps 2 and 4 (see page III-6).

2. If using serum separator tubes (gel in the bottom of the tube, SST) omit steps 2 and 4 above. Be sure the gel forms a distinct barrier between serum and clot.

3. During the summer months, pack all SST specimens with a cold pack since the gel can possibly breakdown at temperatures experienced during the summer months. The breakdown of the gel allows the red blood cells to "leak" into the serum contaminating the specimen and possibly rendering the specimen unacceptable for testing.

4. Always refer to the Public Health Laboratory Services Guide for complete instructions for specimen collection, specimen preparation, specimen storage and specimen transport for the specific laboratory test(s). Note: use current edition only.

5. Never use a gauge needle size smaller than a 23: this can cause hemolysis!

6. Always allow the blood to flow into a vacuum tube without adding additional pressure.

7. DO NOT take disposable tourniquet off until you have collected ALL of the tubes and the tubes are filled: when you take the tourniquet off once you are inside you run the risk of slow blood flow and/or short draws and/or insufficient blood volume.

Specimen Collection: Fingerstick Procedure
For Patients Greater Than 1 Year Old

Hemoglobin or General Laboratory Procedures

Precaution: Wear gloves and liquid resistant lab coat or apron while collecting and preparing blood for shipment.

Supplies: see Clinical Formulary on the intranet for approved supplies

1. Retractable safety lancets: see Clinical Formulary on the intranet for approved lancets for adults and pediatrics
2. 70% isopropyl alcohol pads or benzylkonium chloride pads
3. Sterile gauze pads (NO COTTON BALLS!)
4. Band-aids (optional)
5. Sharps disposal container (with stand or wall mounted)
6. Biohazard waste container

Personal Protective Equipment (PPE) Requirements:

1. Disposable gloves (required during collection)
2. Safety glasses (required if there is any chance of eye/mouth contamination during collection; strongly recommended if wear contact lens)
3. Liquid resistant lab coat or apron (required during collection)
4. Additional protection as recommended by OSHA and/or MSDS

Specimen Collection: You MUST have completed a DHEC Workshop and be rated proficient and competent BEFORE you can collect a fingerstick without direct supervision.

1. While putting on the appropriate PPE, explain the procedure to the patient and ask the patient to identify themselves or check a picture identification card; if a child, ask parent and/or guardian to state child's name.
   a. BEFORE putting on ANY PPE, wash hands with soap and water or use a hand sanitizer with at least 60% alcohol content.
   b. Order for putting on PPE: put eye protection on first (optional), then put on liquid resistant/impervious lab coat/apron, and then put on non-latex gloves.

2. Have all supplies within easy reach and all materials ready to use before performing the fingerstick procedure.

3. Place the sharps disposal container and waste container so you DO NOT have to cross over the patient or yourself when discarding contaminated items.

4. Wash hands with soap and water or use a hand sanitizer with at least 60% alcohol; put on disposable gloves.

5. Instruct the patient to rest his/her arm downward position for about 30 seconds to allow blood flow to the fingertips. If the patient's hand is cold, warm the hand:
   a. Gently massage the finger a few times from the base to the tip of the finger.
   b. Stroke the arm with gentle downward motion from the forearm to the hand.
   c. Ask the patient to briskly rub both hands together.
   d. Use a warm (not more than 105 degrees F.), moist towel on the hand for a couple of minutes.
   e. Ask the patient to wash his/her hands with warm water.

6. Select the middle or ring finger for puncture on the hand used least often.

7. **Do NOT** choose a puncture site on a fingertip that is callused, purple, scarred, swollen, or injured.

8. Use the less painful, fleshy area of the fingertip, just off center to the finger pad, slightly to the side.

9. Clean the puncture site with an alcohol pad or benzylkonium chloride pad.
   a. Wipe in one direction ONLY!
   b. Allow the alcohol or benzylkonium chloride to evaporate.
   c. **Do NOT** blow on the finger or fan the area.

10. **Do NOT** saturate the site with alcohol. Discard the used alcohol pad and wrapper in the regular trash can.

11. Allow the site to air dry completely.

12. Firmly hold the patient's finger, palm side up, between your thumb and index finger.

13. Puncture the site and dispose of the used lancet in the sharps container.
   a. Note: Puncture the finger with the lancet PERPENDICULAR to the ridge swirls on the finger.
   b. Place the lancet FIRMLY on the finger pad site BEFORE triggering the lancet.

14. Wipe away the first 2-3 drops of blood with the sterile gauze.

15. Apply gentle pressure every few seconds, about ½ inches from the puncture site.

16. Collect specimen in a microtube (bullet), or for dried blood spots, or a hemoglobin cuvette.

17. Have patient apply pressure on the site for 2-3 minutes to prevent leakage of blood under the skin and formation of a hematoma. When site is no longer bleeding, a bandage may be applied if desired.
   a. Ask the patient/or parent to hold the gauze on the finger.
   b. If the patient cannot do this, hold the finger for them.

18. Label specimen tube (s) with proper patient identification information; if not already done when getting supplies together.
   a. Name of patient/client (first name and last name).
   b. MCI number or other unique identification number.
   c. Date collected, time collected and initials of person who collected specimen goes on the requisition/lab form.
   d. Note: if you use a HemoCue microcuvette, the frosted edge needs to have patient's last name at least and the date.

19. Complete ALL information on the test request/lab requisition form(s): DHEC 1332/1335.
   a. Name of patient/client (first name and last name).
   b. MCI number or other unique identification number.
   c. Date collected, time collected and initials of person who collected specimen.
   d. Test required
   e. Type of specimen

f. Ordering physician, APRN, RN, DIS
g. Test(s) requested
h. Sender Address or Sender code number
i. Any specimen instructions or other important information
j. Note: if you use a computer label, just add time and initials of person collecting specimen.
k. Note: if you use a computer label, be sure to place the computer label with all demographic information on copy 1, copy 2 and copy 3.
l. You will send the original top copy of the DHEC 1332/1335 with the specimen(s)
m. Retain the third copy for your files in the County Health laboratory.

20. Properly dispose of lancets (in biohazard puncture proof sharps container) and other contaminated materials used during fingerstick.
    a. Place all blood soaked material in the contaminated waste bag (Biohazard).
    b. Place all sharps in the sharps container and DO NOT fill above 2/3!
    c. DO NOT place any non-contaminated waste in the sharps container or Biohazard waste!

21. Remove PPEs in this order:
    a. Remove contaminated gloves.
    b. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
    c. Remove any eye protection.
    d. Remove liquid impervious/resistant lab coat or apron.
    e. Wash hands with soap and water or with hand sanitizer with >60% alcohol.

22. BEFORE allowing the patient/client to leave, take the gauze off of the fingerstick site to ensure it has stopped bleeding.
    a. DO NOT wipe the area with gauze since this will initiate bleeding again (subcutaneous) and may cause a hematoma (bruise).
    b. DO NOT allow patient to get up from the chair, table, etc. without being physically at the side or in front of the patient/client: THIS IS A FALL PREVENTION MEASURE!

Specimen Collection: Fingerstick for Patients Greater Than 1 Year Old

Dried Blood Spots Collection

Precaution: Wear gloves and liquid resistant lab coat or apron while collecting and preparing blood for shipment.

The filter paper to be used in the collection of dried blood spots is attached to the DHEC form 1339 for HEMOGLOBIN ELECTROPHORESIS or the DHEC form 1327 for PKU MONITORING. Envelopes for mailing specimen are also available.

Sufficient blood MUST be obtained from the fingerstick puncture to fill each circle by making a single application of blood to the filter paper. The filter paper should touch only the drop of blood and should not be pressed against the skin around the puncture. Be sure that the filter paper is saturated through with blood. DO NOT superimpose blood drops! This leads to inaccurate results.

Supplies:

1. Retractable safety lancets for infant or pediatric: see Clinical Formulary listings on the intranet for approved lancets
2. 70% isopropyl alcohol or benzylkonium chloride pads
3. Sterile gauze pads (NO COTTON BALLS!)
4. Band-aids (optional)
5. Sharps disposal container (with stand or wall mounted)
6. Biohazard waste container

Personal Protective Equipment (PPE) Requirements:

1. Disposable gloves (required during collection)
2. Safety glasses (required if there is any chance of eye/mouth contamination duringcollection; strongly recommend if wear contact lens)
3. Liquid resistant lab coat or apron (required during collection)
4. Additional protection as recommended by OSHA and/or MSDS

Specimen Collection:

1. While putting on the appropriate PPE, explain the procedure to the patient and ask the patient to identify themselves or check a picture identification card; if a child, ask parent and/or guardian to state child's name.
   a. BEFORE putting on ANY PPE, wash hands with soap and water or use a hand sanitizer with at least 60% alcohol content.
   b. Order for putting on PPE: put eye protection on first (optional), then put on liquid resistant/impervious lab coat/apron, and then put on non-latex gloves.

2. Have all supplies within easy reach and all materials ready to use before performing the fingerstick procedure.

3. Place the sharps disposal container and waste container so you **DO NOT** have to cross over the patient or yourself when discarding contaminated items.

4. Wash hands with soap and water or use a hand sanitizer with at least 60% alcohol; put on

disposable gloves.

5. Instruct the patient to rest his/her arm downward position for about 30 seconds to allow blood flow to the fingertips. If the patient's hand is cold, warm the hand:
   a. Gently massage the finger a few times from the base to the tip of the finger.
   b. Stroke the arm with gentle downward motion from the forearm to the hand.
   c. Ask the patient to briskly rub both hands together.
   d. Use a warm (not more than 105 degrees F.), moist towel on the hand for a couple of minutes.
   e. Ask the patient to wash his/her hands with warm water.
6. Select the middle or ring finger for puncture on the hand used least often.

7. **Do NOT** choose a puncture site on a fingertip that is callused, purple, scarred, swollen, or injured.

8. Use the less painful, fleshy area of the fingertip, just off center to the finger pad, slightly to the side.

9. Clean the puncture site with an alcohol pad or benzylkonium chloride pad.
   a. Wipe in one direction **ONLY**!
   b. Allow the alcohol or benzylkonium chloride to evaporate.
   c. **Do NOT** blow on the finger or fan the area.

10. **Do NOT** saturate the site with alcohol.
    Note: Discard the used alcohol pad and wrapper in the regular trash can.

11. Allow the site to air dry completely.

12. Firmly hold the patient's finger, palm side up, between your thumb and index finger.

13. Puncture the site and dispose of the used lancet in the sharps container.
    a. Note: Puncture the finger/heel with the lancet PERPENDICULAR to the ridge swirls on the finger.
    b. Place the lancet FIRMLY on the finger pad/heel site BEFORE triggering the lancet.

14. Wipe away the first drop of blood with the sterile gauze.

15. Apply gentle pressure every few seconds, about ½ inches from the puncture site.

16. Collect specimen onto filter paper for dried blood spots.

17. Have patient apply pressure on the site for 2-3 minutes to prevent leakage of blood under the skin and formation of a hematoma. When site is no longer bleeding, a bandage may be applied if desired.
    a. Ask the patient/or parent to hold the gauze on the finger.
    b. If the patient cannot do this, hold the finger for them.

18. Complete ALL information on the 1327 or 1339 form:
    a. Name of patient/client (first name and last name).
    b. MCI number or other unique identification number.
    c. Date collected, time collected and initials of person who collected specimen.
    d. Ordering physician, APRN, RN, DIS
    e. Complete submitter and/or physician information.

f. You will send the original top copy of the DHEC 1327/1339 with the specimen(s).
g. Retain the middle copy for your files.

19. Properly dispose of lancets (in biohazard puncture proof sharps container) and other contaminated materials used during fingerstick.
    a. Place all blood soaked material in the contaminated waste bag (Biohazard).
    b. Place all sharps in the sharps container and **DO NOT** fill above 2/3!
    c. **DO NOT** place any non-contaminated waste in the sharps container or Biohazard waste!

20. Remove PPEs in this order:
    a. Remove contaminated gloves.
    b. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
    c. Remove any eye protection.
    d. Remove liquid impervious/resistant lab coat or apron
    e. Wash hands with soap and water or with hand sanitizer with >60% alcohol.

21. BEFORE allowing the patient/client to leave, take the gauze off of the fingerstick site to ensure it has stopped bleeding.
    a. **DO NOT** wipe the area with gauze since this will initiate bleeding again (subcutaneous) and may cause a hematoma (bruise).
    b. **DO NOT** allow patient to get up from the chair, table, etc. without being physically at the side or in front of the patient/client: THIS IS A FALL PREVENTION MEASURE!

Special Procedural Notes for Dried Blood Spots:

1. When properly filled, the blood spot will be the same size on both sides of the filter paper.

2. **DO NOT** send the specimen if the circles are not completely filled—collect a second sample.
3. All the circles are needed. If tests have to be repeated or additional tests need to be run, all 5 circles are required.

Troubleshooting:

1. Failure to wipe off alcohol residue may dilute the specimen and adversely affect test results.

2. Puncturing the heel on posterior curvature will permit blood to flow away from puncture, making proper spotting difficult.

3. **DO NOT** lance on previous puncture site.

4. Use of a capillary tube is not recommended since application of blood with a capillary tube results in scratching and/or abrading the surface of the filter paper which adversely affects test results.

5. Avoid touching area within filter paper circles before blood is applied.

6. **DO NOT** place filter paper in the envelope until thoroughly dry.

7. INSUFFICIENT DRYING ADVERSELY AFFECTS TEST RESULTS!

Specimen Collection: Heel-stick Procedure
For Patients Less Than 1 Year Old

Hemoglobin or General Laboratory Testing or Newborn Screening

Precaution: Wear gloves and liquid resistant lab coat or apron while collecting and preparing blood for shipment.

Supplies: see Clinical Formulary on the intranet for approved supplies

1. Retractable safety lancets: Tenderfoot™ or lancet giving 1.0 mm – 2.0 mm depth
2. 70% isopropyl alcohol or benzylkonium chloride pads
3. Sterile gauze pads **(NO COTTON BALLS**!)
4. Band-aids (optional)
5. Sharps disposal container (with stand or wall mounted)
6. Biohazard waste container

Personal Protective Equipment (PPE) Requirements:

1. Disposable gloves (required during collection)
2. Safety glasses (required if there is any chance of eye/mouth contamination during collection; strongly recommend if wear contact lens)
3. Liquid resistant lab coat or apron (required during collection)
4. Additional protection as recommended by OSHA and/or MSDS

Personal Protective Equipment (PPE) Requirements:

1. Disposable gloves (required during collection)
2. Safety glasses (required if there is any chance of eye/mouth contamination during collection)
3. Liquid resistant lab coat or apron (required during collection)
4. Closed-toe shoes MUST be worn when collecting ANY blood specimens
5. Additional protection as recommended by OSHA and/or MSDS

Specimen Collection: You MUST have completed a DHEC Workshop and be rated proficient and competent BEFORE you can collect a fingerstick without direct supervision.

1. While putting on the appropriate PPE, explain the procedure to the patient and ask the patient to identify themselves or check a picture identification card; if a child, ask parent and/or guardian to state child's name.
   a. BEFORE putting on ANY PPE, wash hands with soap and water or use a hand sanitizer with at least 60% alcohol content.
   b. Order for putting on PPE: put eye protection on first (optional), then put on liquid resistant/impervious lab coat/apron, and then put on non-latex gloves.

2. Have all supplies within easy reach and all materials ready to use before performing the heelstick procedure.

3. Place the sharps disposal container and waste container so you **DO NOT** have to cross over the patient or yourself when discarding contaminated items.

4. Wash hands with soap and water or use a hand sanitizer with at least 60% alcohol; put on disposable gloves.

5. Instruct the parent/guardian to rest the leg of the infant in a downward position for about 30 seconds to allow blood flow to the foot. If the patient's foot is cold, warm the foot:
   a. Gently massage the foot/heel a few times from the base to the tip of the heel.
   b. Stroke the heel with gentle downward motion from the ankle to the toes.
   c. Ask the patient to briskly rub both hands together.
   d. Use a warm (not more than 105 degrees F.), moist towel on the heel for a couple of minutes.
   e. Ask the parent/guardian to wash child's foot/heel with warm water.

6. Select the heel for puncture.
   Note: Use **ONLY** the lateral or medial sides of the heel.

   Note: **DO NOT** use the plantar region of the foot or great toe.

7. **Do NOT** choose a puncture site on a heel that is callused, purple, scarred, swollen, or injured.

8. Get all microcuvettes ready and LABEL NOW!!! Use a #2 pencil or black Sharpie.

9. Clean the puncture site with an alcohol pad or benzylkonium chloride pad.
   a. Wipe in one direction ONLY!
   b. Allow the alcohol or benzylkonium chloride to evaporate.
   c. Do NOT blow on the finger or fan the area.

10. Do NOT saturate the site with alcohol.
    a. Remove excess alcohol with a clean gauze pad.
    b. Discard the used alcohol pad and wrapper in the regular trash can.

11. Allow the site to air dry completely.

12. Firmly hold the patient's heel between your thumb and index finger.

13. Puncture the site and dispose of the used lancet in the sharps container.
    a. Note: Puncture the heel with the lancet PERPENDICULAR to the ridge swirls on the heel.
    b. Place the lancet FIRMLY on the heel site BEFORE triggering the lancet.

14. Wipe away the first 2-3 drops of blood with the sterile gauze.

15. Apply gentle pressure every few seconds, about ½ inches from the puncture site.

16. Collect specimen in a microtube (bullet), or for dried blood spots, or a hemoglobin cuvette. LABEL NOW!!

17. Have patient apply pressure on the site for 2-3 minutes to prevent leakage of blood under the skin and formation of a hematoma. When site is no longer bleeding, a bandage may be applied if desired; elevate the leg higher than the heart.
    a. Ask the parent to hold the gauze on the puncture site.
    b. If the parent cannot do this, hold the heel elevated above the heart.

18. Label specimen tube (s) with proper patient identification information; if not already done when getting supplies together.
    a. Name of patient/client (first name and last name).

b. MCI number or other unique identification number.
c. Date collected, time collected and initials of person who collected specimen goes on the requisition/lab form.
d. Note: if you use a HemoCue microcuvette, the frosted edge needs to have patient's last name at least and the date.

19. Complete ALL information on the test request/lab requisition form(s): DHEC 1332/1335.
    a. Name of patient/client (first name and last name).
    b. MCI number or other unique identification number.
    c. Date collected, time collected and initials of person who collected specimen.
    d. Test required
    e. Type of specimen
    f. Ordering physician, APRN, RN, DIS
    g. Test(s) requested
    h. Sender Address or Sender code number
    i. Any specimen instructions or other important information
    j. Note: if you use a computer label, just add time and initials of person collecting specimen.
    k. Note: if you use a computer label, be sure to place the computer label with all demographic information on copy 1, copy 2 and copy 3.
    l. You will send the original top copy of the DHEC 1332/1335 with the specimen(s).
    m. Retain the third copy for your files in the County Health laboratory.

20. Properly dispose of lancets (in biohazard puncture proof sharps container) and other contaminated materials used during heelstick.

    a. Place all blood soaked material in the contaminated waste bag (Biohazard).
    b. Place all sharps in the sharps container and **DO NOT** fill above 2/3!
    c. **DO NOT** place any non-contaminated waste in the sharps container or Biohazard waste!

21. Remove PPEs in this order:
    a. Remove contaminated gloves.
    b. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
    c. Remove any eye protection.
    d. Remove liquid impervious/resistant lab coat or apron.
    e. Wash hands with soap and water or with hand sanitizer with >60% alcohol.

22. BEFORE allowing the patient/client to leave, take the gauze off of the puncture site to ensure it has stopped bleeding.
    a. **DO NOT** wipe the area with gauze since this will initiate bleeding again (subcutaneous) and may cause a hematoma (bruise).

    b. **DO NOT** allow parent/patient to get up from the chair, table, etc. without being physically at the side or in front of the parent/patient: THIS IS A FALL PREVENTION MEASURE!

Special Procedural Notes for Dried Blood Spots:
1. When properly filled, the blood spot will be the same size on both sides of the filter paper.

2. **DO NOT** send the specimen if the circles are NOT completely filled—collect a second sample.

2. All the circles are needed. If tests have to be repeated or additional tests need to be run, all 5 circles are required.

Troubleshooting:

1. Failure to wipe off alcohol residue may dilute the specimen and adversely affect test results.

2. Puncturing the heel on posterior curvature will permit blood to flow away from puncture, making proper spotting difficult.

3. **DO NOT** lance on previous puncture site.

4. Use of a capillary tube is not recommended since application of blood with a capillary tube results in scratching and/or abrading the surface of the filter paper which adversely affects test results.

5. Avoid touching area within filter paper circles before blood is applied.

6. **DO NOT** place filter paper in the envelope until thoroughly dry.

7. INSUFFICIENT DRYING ADVERSELY AFFECTS TEST RESULTS!

HEPATITIS C (HCV)
TOTAL ANTIBODY and QUANTITATION (RNA)

Note: This test is only available for DHEC HCV project sites or by special request

Principle:
To properly collect a blood specimen for Hepatitis C, total antibody testing by EIA and /or PCR Quantitation (RNA)

Patient preparation:
No special preparation

Supplies:
1. 1 Serum separator tube
2. Cold packs for shipping
3. DHEC form1332

Collection Procedure:
Precaution: Wear gloves when collection blood samples

1. Use serum separator tube, and Collect a full tube of blood
2. Allow to clot at room temperature and centrifuge within four hours of collection. Invert the tube after centrifugation to verify that the serum separator is intact and no cells enter the serum. If cells enter the serum, repeat centrifugation. Same specimen can be used for both tests

Specimen Handling:
1. Write the patient's name on the serum separator tube or use a patient label.
2 Complete a DHEC form 1332. See instructions on back of form for completing. Mark test # 224 and mark test 227 for the PCR Quantitation (RNA) only

Specimen Preservation and Transport
1. Place the sample in a container with enough cold packs to maintain a temperature of 2º to 8º C during shipment. Sample must arrive at the laboratory within 24 hours of collection.
2. Label the outside of the container as HCV Viral Load
3. See Section IV for appropriate shipping container, packaging and transport instructions.

Causes for Specimen Rejection:
1. Serum separator tube not used
2. Specimen not shipped with cold packs or specimen not cold on arrival.
3. Universal rejections, See Section I.

QuantiFERON-TB Gold Plus (QFT-Plus) Collection Procedure

Principle:
To properly collect a blood specimen for QuantiFeron-TB Gold Plus.

Supplies:
1. 4 QFT tubes
2. DHEC form 1335
3. Designated QFT shipper

Collection Procedure:

Precaution: Wear gloves when collecting blood samples

1. For each patient, collect 1mL of blood by venipuncture directly into each of the QFT-Plus blood collection tubes (4 tubes total).
    a. As 1 mL tubes draw blood relatively slowly, keep the tube on the needle for 2-3 seconds once the tube appears to have completely filled, to ensure that the correct volume is drawn. *Note: The black mark on the side of the tubes indicates 1mL fill volume. QFT-Plus blood collection tubes have been validated for volumes from 0.8 mL- 1.2 mL. If the level of blood is outside the indicator line, it is recommended to obtain another blood sample.*
    b. If a butterfly needle is being used to collect blood, a "purge" tube should be used to ensure that the tubing is filled with blood prior to the QFT-Plus tubes being used.
2. Immediately after filling tubes, shake them ten (10) times just firmly enough to ensure the entire inner surface of the tube is coated with blood to dissolve the antigens on the tube walls
    a. Tube temperature should be between 17-25°C at the time of blood tube filling.
    b. Overly vigorous shaking may cause gel disruption and could lead to aberrant results.
3. Label tubes appropriately.
4. The tubes must be transferred to a 37°C ± 1°C incubator as soon as possible, and within 16 hours of collection. Prior to incubation, maintain the tubes at room temperature (22°C ± 5°C). Do not refrigerator or freeze the blood samples. *Note: There are incubators located at specific sites in the regions, or samples can be placed on courier for incubation* ***HOWEVER*** *samples must be received within the acceptable 16 hours post-collection if incubation is to occur at the Public Health Laboratory.* If the blood is not incubated immediately after collection, re-mixing of the tubes by inverting 10 times must be performed immediately prior to incubation at 37ºC.
5. Incubate the tubes **UPRIGHT** at 37°C ± 1°C for 16-24 hours.
6. After incubation at 37°C, blood collection tubes may be held between 4-27°C for up to 3 days before further testing. Specimens should be shipped to the Virology laboratory using the courier system in the designated boxes within the 3 day post-incubation time period.

Specimen Handling:
1. Use a patient label to properly label each QFT-Plus tube.
2. Complete a DHEC 1335. See instructions on back of form for completing. Mark QuantiFeron Gold-Plus and complete incubation start and end time.

Specimen Preservation and Transport:
1. Specimens should be shipped and received within 16 hours of collection if not incubated in regions or within 3 days post-incubation.

2. Place the specimen inside designated QFT-Plus shipper (large white shipper with pink label) and ship at room temperature (17-25°C) via the state courier system.

Specimen Rejection:

1. Universal Rejections, See Section 1
2. Use of improper collection techniques and/or under- or over-filled collection tubes.
3. Sample not incubated within the proper incubation period after collection (samples under- or over-incubated) or samples requiring incubation at 37°C are not received at the Public Health Laboratory within 16 hours of collection.

ENTERIC PATHOGENS

Principle:

To properly collect a stool specimen for the isolation of the following enteric pathogens: *E coli 0157, Salmonella, Shigella, Yersinia, Campylobacter, Vibrio, Staphylococcus, Clostridium perfringens and Bacillus cereus.*

Patient Preparation:
No special preparation.

Supplies:
1. Wide-mouthed container.
2. Enteric kit with Cary-Blair transport media. See Page III-1 to order.
3. DHEC form 1335

Collection Precautions:
Wear gloves when collecting stool specimens.

Collection Procedure (Stool):
1. Collect stool in a clean (not necessarily sterile) wide-mouthed container with a tight-fitting lid. These containers must be free of preservatives and detergents.
2. **Do not collect specimen from toilet. Avoid contamination with urine**.
3. Infant specimens may be collected in a disposable diaper with plastic side facing inside.
4. Collect a walnut sized piece if stool is formed or 5-10 ml if stool is liquid.

Cary-Blair Transport media
Formed feces: use tongue depressor or spoon inside the lid to transfer walnut size portion of stool. Liquid feces: use pipette to transfer 5-10 ml of liquid stool to the transport media. Replace cap on tube and refrigerate until transported.

Specimen Handling:
1. Place a patient identification label on the transport medium
2. Complete a DHEC form 1335 to accompany specimen. See instructions on back of form. Be sure to complete additional test specific information
   Specimen Type/Source: Mark X by Feces
   Date Collected
   Organism Suspected: Indicate name of suspected organism
   NOTE: Routine culture includes testing for Salmonella, Shigella, Campylobacter, and E. coli 0157. Request for other specific pathogens must be indicated on the laboratory request form.
   Test Requested: Mark 508 Enteric Culture.

Specimen Preservation and Transport:
1. Ship specimens in transport media in cooler with cold packs. Specimen should be received within 48 hours of collection.
2. See Section IV for appropriate shipping container, packaging and transport instructions.

Specimen Rejection:
1. Specimen too old.
2. Use of improper transport media or transport conditions.
3. Insufficient quantity
4. Universal rejections, See Section I

NEISSERIA GONORRHOEAE

Principle:

To properly collect an eye culture, rectal culture and oropharyngeal culture for the diagnosis of *Neisseria gonorrhoeae.* To properly collect a cervical, urethral and vaginal culture in cases of assault or sexual abuse.

Patient Preparation:

For male urethral culture: The patient should not have voided for at least 1 hour before performing a culture, especially men without a discharge.

Supplies:

1. Sterile Dacron or Rayon swab
2. Sterile thin, flexible wire with Dacron or Rayon swab (males)
3. GC culture kit with Transgrow bottle for *N. gonorrhoeae* See Page III-1 to order.
4. DHEC form 1335
5. Speculum (cervical, vaginal)

Collection Precautions: (All specimens)

Wear disposable gloves And protective eye wear when collecting and handling specimens.
Note: Collect all specimens Monday - Wednesday. Do not ship for weekend delivery.

Collection Procedure: (Eye)

1. Touch a sterile swab to purulent discharge. If necessary, lower eyelid may be pulled down and the swab touched to the conjunctival mucosa.
2. Inoculate Transgrow bottles as described under Inoculation of Transgrow medium

Collection Procedure: (Rectal)

1. Have the patient bear down slightly for ease in insertion of swab.
2. Insert a sterile swab approximately 3 cm into the anal canal using lateral pressure to avoid entering any fecal mass. If gross fecal contamination of the swab occurs, it should be discarded into a biohazard container and a repeat specimen obtained.
3. Rotate the swab to sample crypts just inside the anal ring and allow the swab to remain in the anal area for several seconds for better absorption onto the swab.
4. Inoculate Transgrow bottles as described under Inoculation of Transgrow medium.

Collection Procedure: (Oropharyngeal [Throat])

1. Using a tongue blade to hold the tongue down, take a specimen directly from the back of the throat, carefully avoiding contact with teeth, cheeks, gums or tongue when inserting or removing the swab.
2. Rub a sterile swab over the back wall of the throat and tonsillar crypts.
3. Inoculate Transgrow bottles as described under Inoculation of Transgrow Medium.

Collection Procedure: (Cervical)

1. Obtain the cervical specimen with the aid of a speculum that has been moistened with water. Other lubricants may contain antibacterial agents.
2. Insert the speculum and if unable to visualize the cervical os, remove excess mucus with swab.
3. Insert another sterile swab into the endocervical canal approximately 2-3 cm. Move the swab in a rotary motion for a few seconds to permit absorption of the exudate. If the patient is pregnant, and there has been no vaginal bleeding, insert swab into the endocervix only until the tip is no longer visible and rotate gently for a few seconds).
4. Inoculate Transgrow bottles as described under inoculation of Transgrow medium.

Collection Procedure: (Vaginal) for Children and Hysterectomy Patients Only

1. Insert the speculum.
2. With a sterile swab obtain the specimen from the posterior vaginal vault.
3. Allow a few seconds for absorption of material.
4. If the hymen is intact, a swab of the vaginal orifice will suffice.
5. Inoculate Transgrow bottles as described under Inoculation of Transgrow medium.

Collection Procedure: (Urethral Culture - Females)

1. Massage the urethra against the pubic symphysis from vagina to orifice to express discharge.
2. If no discharge is evident, insert a sterile flexible thin wire swab approximately 2 cm into the urethra and rotate for several seconds.
3. Withdraw swab and inoculate Transgrow bottle as described under Inoculation of Transgrow

Collection Procedure: (Urethral - Males)

1. Insert a sterile flexible swab with a thin wire shaft 2-4 cm into the urethra.
2. Once inserted, rotate the swab gently to ensure contact with all urethral surfaces.
3. Leave inserted for 2-3 seconds for better absorption of material.
4. Withdraw swab and inoculate Transgrow bottle as described under Inoculation of Transgrow.

Inoculation of Transgrow Medium

1. Have Transgrow at **room temperature; check the expiration date** before inoculation.
2. Hold the bottle in an upright position. Remove the cap only when ready to inoculate.
3. Soak up excess moisture in the bottle with the specimen swab and roll the swab from side to side over the entire surface of the medium starting at the bottom of the bottle.
4. Remove swab from bottle and discard into a biohazard container.
5. Recap the bottle tightly.

Specimen Handling:

1. Place label with patient's name on back of Transgrow bottle where chocolate colored medium is layered. **Do not place label on clear side of bottle**. This window is needed to observe growth.
2. Complete a DHEC form 1335 to accompany specimen. See instructions on back of form. Be sure to complete test specific information.

   Specimen: Mark X by the appropriate type and write in the site.
   Was Culture Incubated Before Transport?: mark X in the appropriate space(s).
   Test Requested: Mark X in the appropriate space.

Specimen Preservation and Transport:

1. Place the Transgrow bottle in an upright position in an incubator set at 35°C as soon as possible after inoculation. **Never refrigerate the medium after inoculation as cold temperature will rapidly kill gonococci.** Incubate until ready to ship,
2. If an incubator is not available, make sure culture is shipped on the same day as collected.
3. If the specimen is collected on Friday and cannot be shipped until Monday, incubate over the weekend, but remove first thing Monday morning to prevent contaminant overgrowth.
4. Note: Do not ship for weekend delivery.

Specimen Rejection:

1. Transgrow media not used or Transgrow media expired.
2. Specimen in transit for more than 5 days.
3. Universal rejections, See Section I.

DIPHTHERIA

Principle:

To properly collect a throat swab for the culture of *C. diphtheria*

Patient Preparation:

No special preparation

Supplies:

1. Culturette swab kit containing Stuart's medium. Use form 1323 to order and indicate culturette in blank space on form.
2. DHEC form 1335

Collection Procedure for Throat Swab:

1. Shine a bright light if possible over the shoulder of the specimen collector into the oral cavity of the patient so that the swab can be guided to the posterior pharynx.
2. The patient is instructed to tilt his/her head back and breathe deeply.
3. Depress the tongue with a tongue depressor to help visualize the posterior pharynx. Use culturette kit. Do not use calcium alginate swabs.
4. Extend the swab to the back of the throat between the tonsillar pillars and behind the uvula.
5. Have the patient phonate a long aah which will lift the uvula and help to prevent gagging.
6. The tonsillar areas and posterior pharynx should be firmly rubbed with the swab.
7. Care should be taken not to touch the teeth, cheeks, gums or tongue when inserting or removing the swab to minimize contamination with normal mouth flora.
8. After collection, place the swab back into the culturette and break or squeeze the ampule. Note: Notify the DHEC Bacteriology Section (803-896-0805) when a diphtheria specimen is to be collected so that special isolation media can be prepared.

Specimen Handling

1. Place a patient label on a culturette swab kit.
2. Organism suspected: Indicate *Corynebacterium diphtheriae*.

Specimen Preservation and Transport

1. Store and ship culturette at room temperature. Note: Transport within 24 hours. Do not ship for weekend delivery.
2. See Section IV for appropriate shipping container, packaging and transport instructions.

Specimen Rejection

1. Ampule in culturette not crushed.
2. Universal rejections, See Section I.

MYCOBACTERIUM (TB)

Principle:
To properly collect a sputum or urine specimen for the diagnosing and monitoring of tuberculosis and other mycobacterial infections.

Supplies:
1. (a) Mycobacteriology collection kit (50 ml plastic sputum collection tube, metal can and cardboard mailing container) See Page III-1 to order.
   (b) Sterile screw cap container with a round opening of at least 2 inches for urine
2. DHEC form 1335
3. Particulate respirator (PR)

Collection Procedure: (All Specimens)
Wear Disposable Gloves and a Particulate Respirator When Collecting Specimens

Patient Preparation: (Sputum)
1. Explain to patient the importance of how to collect and handle a sputum specimen. Give the patient the sputum collection kit and COLLECTION OF SPUTUM SPECIMENS FOR MYCOBACTERIA (TB) sheet.
2. If the nurse must remain with the patient while he/she is coughing, the nurse should wear a particulate respirator.
3. Have the patient collect an early morning sputum sample.
4. Ask the patient to breathe deeply, exhale, and then cough deeply. Steam from a hot shower or a boiling kettle may help to stimulate the flow of secretions. Also, drinking several cups non alcoholic liquids will assist in raising sputum.
5. Patient should brush his/her teeth and/or rinse with water, not an antiseptic solution before obtaining the sputum specimen to reduce the overgrowth of mouth flora,
6. The patient should submit a series of three (3) sputum samples over a period of three days (one/day), if specimens are being collected for initial diagnosis.

Collection Procedure (Sputum)
1. Remove the cap from the sterile container without touching the inside of the container. This will avoid contamination of the specimen which results in having to submit another specimen.
2. Patient is instructed to take a deep breath, hold it momentarily and cough deeply from the deepest part of the chest. Saliva and nasal secretions which contain few acid-fast bacteria are not to be collected.
3. Instruct the patient to spit the sputum into the appropriate sterile container until at least 5 ml or 1 teaspoon is obtained. Replace cap on the container. A minimum of 5 ml is needed for culture.
4. Avoid soiling the outside of the container. If soiling does occur, wipe with a clean cloth wet with alcohol soap and water, or 1:10 bleach solution, and then wash hands.
5. Sputum specimens should be free of food particles and other extraneous material.
6. Place the cap on plastic tube or sterile container and screw to close tightly.

If patient is to collect sputum in the home, give patient sputum collection and mailing containers and instruction sheet on how to obtain a sputum sample.

Collection Procedure: (Urine)

The patient should submit a series of three (3) urine samples over a period of three days (one/day) if specimens are being collected for initial diagnosis.

Female- midstream voided:

1. Have patient thoroughly clean the urethral area with soap and water.
2. Instruct patient to sit on toilet, and to manually separate labia minora with one hand and keep them separated while voiding the first portion of urine into the toilet.
3. After several ml have passed, have patient collect the midstream portion into the specimen container without stopping the flow of urine. Try to avoid touching the lip or inside of the container with the hand.
4. Have the patient finish voiding into the toilet.
5. Amount of urine needed is 10 ml. Screw cap on plastic tube to close tightly.

Male-midstream voided:

1. Clean the glans with soap and water.
2. While holding foreskin retracted, begin voiding.
3. After several ml have passed collect the midstream portion into the appropriate container without stopping flow of urine.
4. Have the patient finish voiding into the toilet.
5. Amount of urine needed is 10 ml. Screw cap on plastic tube to close tightly.

For collection procedures on other specimens see chart on Collection and Shipment of Mycobacterial Specimens.

Specimen Handling:

1. Place a patient identification label on the 50 ml screw capped tube.
2. Complete a DHEC form 1335 to accompany specimen See instructions on back of form. Be sure to complete test specific information:

   Agent suspected: Enter the suspected agent

   Specimen source: Mark "X" by the appropriate source.

   Date & Time Collected:

   NOTE: All clinical specimens should be ordered using Test Code 601. Test Code 602 is reserved exclusively for laboratories that have isolated Mycobacteria and need them identified. Do not request drug susceptibility testing (Test Code 604) when submitting specimens from suspected new cases of tuberculosis. All initial isolates of M. tuberculosis will be tested for susceptibility to INH, rifampin, ethambutol, streptomycin and pyrazinamide.

Specimen Preservation and Transport: Sputum:

1. Refrigerate samples if shipping is delayed over 24 hours. This will decrease overgrowth of other microorganisms which delay culture results.
2. Place the collection tube in the metal can and close screw cap securely. Be sure neither plastic tube nor metal can are soiled with sputum or urine.
3. Wrap the completed DHEC 1335 laboratory form around the metal can. Be sure the date the specimen was collected is on the form. If the laboratory form is around the plastic tube instead of the metal can the laboratory must autoclave it before it can be handled.
4. Place the metal can in the pre-addressed, round cardboard mailing container
5. Mail specimen on the day it was collected, if possible, but do not mail specimen on Fridays. Refrigerate the carton until mailed.

Specimen Preservation and Transport Urine.

1. If specimen is urine, ship cold with cold packs.
   Place a plastic bag over the fiberboard carton and place in a Styrofoam cooler with cold packs for transportation.
2. Label outside of cooler as Urine for TB testing

Specimen Rejection:

1. Specimen broken or leaked in transit. Sterile body fluids may be processed with the approval of the Supervisor or Division Director.
2. Specimen > 5 days old.
3. Universal rejections, See Section I

SPECIMEN COLLECTION FOR CULTURE OF MYCOBACTERIA (TB)

SPECIMEN TYPE	TIME	AMOUNT	NUMBER	SPECIAL PROCEDURE
Sputum	Early AM On Waking	5-10 ml.	Series of 3 One/Day	Sputum-material coughed up from deep in lungs-not saliva
Urine	Early AM	Entire specimen, centrifuge 10 ml.	Series of 3 One/Day	Voided midstream specimen collected as aseptically as possible. Transport to lab immediately.
Gastric Washing	Early AM	10 ml.	1 or more as needed	No food after midnight. Pass 20-50 ml. sterile distilled water through stomach tube and draw off specimen in sterile tube.
Biopsy				No fixative or preservatives (saline only)
Feces		Formed-send walnut sized portion Liquid-send 10 ml.	1 or more as needed	
Sterile body fluids other than blood		10 ml.	1 or more as needed	
Swabs of drainage or other material				Use small amt of sterile saline to keep swab moist. **Do not use transport media. Swabs are not usually productive specimens for mycobacteria.**

Use a Mycobacteriology (TB) collection kit for all specimen types

VIRAL CULTURE
(STOOL)

Principle:

To properly collect a stool specimen for the identification of Enteroviruses and Rotavirus. Specimens should be collected as early as possible during illness.

Patient Preparation:
No special preparation.

Supplies:
1. Wide-mouthed container.
2. Tongue depressor
3. DHEC form 1335
4. Viral Transport media if collecting rectal swab. See Page III-1 to order.

Collection Precaution:
WEAR GLOVES WHEN HANDLING ALL STOOL SPECIMENS.

Collection Procedure (Stool)
1. Collect stool in a clean (not necessarily sterile) wide-mouthed container that can be covered with a tight-fitting lid. These containers should be free of preservatives and detergents.
2. DO NOT COLLECT SPECIMEN FROM TOILET. CONTAMINATION WITH URINE SHOULD BE AVOIDED.
3. Infant specimens may be collected in a disposable diaper with plastic side facing inside.
4. Collect Solid walnut sized piece if stool is formed. Collect 5-10 ml if stool is liquid
5. Place in a dry collection cup. Secure top with tape.
   NOTE: If stool cannot be collected, a rectal swab may be collected. Swab should be placed in viral transport medium

Specimen Handling:
1. Place a patient identification label on the container.
2. Complete a DHEC form 1335 to accompany specimen See instructions on back for completing. Be sure to complete test specific information:
   Specimen: Mark "X" in the appropriate space. If "Other" is marked, enter specimen site.
   Date of Onset: Enter month, day and year.
   Symptoms: Mark each symptom that applies. If "Other" is marked, write in symptom(s).
   Test Requested: Mark "X" in the appropriate space.
   Virus Suspected: Enter name of virus suspected.

Specimen Preservation and Transport:
1. Store in refrigerator and ship cold with cold packs within 24-48 hours after collection
2. If shipping is delayed, freeze at -70ºC and ship on dry ice.
2. Transport medium is advantageous for virus isolation from swabs.

Specimen Rejection:
1. Specimen not cold on arrival
2. Calcium alginate swab used for collection of rectal swab.
3. Universal rejections, See Section I.

Viral Culture/Respiratory Culture/Herpes Culture
(Non-Stool Specimen)

Principle:

To properly collect a buccal swab, throat swab, NP swab, rectal swab, lower or upper respiratory specimen.

Patient Preparation:
No special preparation.

Supplies:

1. Swab with polyester tip. **Do not use calcium alginate swab or wooden shaft swab.**
2. Viral transport media. Store transport media at 2-25ºC until needed.
3. DHEC form 1335

Collection Procedure for Swab (NP, Throat, Buccal, Rectal, Genital Lesions, and/or Ulcers):

1. Swab desired area with appropriate polyester tipped swab.
2. Remove swab and immediately place into viral transport media. Break off swab shaft and close viral transport media container tightly.

Collection Procedure for CSF, lower respiratory, upper respiratory

1. Place fluid into sterile container. Fluid does not need to be placed into viral transport media or saline.

Specimen Handling:

1. Place a patient label on vial of viral transport media.
2. Complete a DHEC form 1335 to accompany specimen. See instructions on back for completing. Be sure to complete test specific information:
   Specimen: Mark X in the appropriate space. If Other is marked, enter specimen site.
   Date of Onset: Enter month, day and year.
   Symptoms: Mark each symptom that applies. If Other is marked, write in symptom(s).
   Test Requested: Mark X in the appropriate space.
   Virus Suspected: Enter name of virus suspected.

Specimen Preservation and Transport

1. Store and ship viral transport tubes cold with cold packs within 24-48 hours after collection or at room temperature.
2. Fluids should be shipped cold with cold packs within 24-48 hours after collection.
3. See Section IV for appropriate shipping container, packaging and transport instructions.

Specimen Rejection

1. Use of calcium alginate swabs.
2. Use of wooden shaft swabs.
3. Universal rejections, See Section I.

BORDETELLA PERTUSSIS DETECTION BY PCR

Principle:

To properly collect nasopharyngeal swabs for the detection of *Bordetella pertussis* by PCR.

I. PCR:

Collection Kit* will contain:

2 nasopharyngeal swabs with **polyester** tips for PCR
1 tube for PCR
1 Request Form (DHEC 1335)
1 instruction sheet

Instructions for collection of NP specimens:

1. Insert a thin swab with a flexible wire into the right nare. The swab is introduced flat and then pushed forward with gentle downward pressure on the lower nasal floor to the posterior wall of the nasopharynx. The swab is rotated for a few seconds before it is gently withdrawn. **Note: Throat swabs are not acceptable. Use swab with polyester tip. Do not use calcium alginate, cotton, or Rayon swab.**
2. Place the swab into the tube of viral transport media.
3. Repeat steps 1 and 2 for the left nare. Label the tube with the patient's name.
4. Complete 1 Request Form (DHEC 1335) to accompany the tubes. Include patient information, date collected, sender name and number, and mark the following boxes:
   Specimen Type/Source: Mark "X" on the 52 (NP) line.
   Organism Suspected: *Bordetella pertussis*
   For PCR requests: Check Test #115 *Bordetella pertussis* PCR.
   If the patient has had antibiotic treatment, please note the drug and when treatment started.
5. Transport the PCR swabs on a cold pack in an insulated, crush-proof container. Be sure to include the request form. Send to the attention of Virology & Rabies at the PUBLIC HEALTH LABORATORY.
6. Specimen Preservation and Transport: If shipping is delayed, the PCR tubes can be stored at 4°C. for 24-48 hours.

*For information on submitting specimens for PCR, please contact the DHEC Virology Laboratory at (803) 896-0819. For kits, please contact the DHEC Public Health Laboratory Supply Section at (803) 896-0913.

CHLAMYDIA/GC & TRICHOMONAS VAGINALIS: GEN-PROBE APTIMA COMBO 2 PROCEDURE

(Endocervical, Male Urethral, Male/Female Rectal, Pharyngeal, Vaginal Specimens)

Principle:

To collect and appropriately handle specimens for nucleic acid amplification testing for Chlamydia and/or Gonorrhoeae testing from male urethral, female genital (cervical or endocervical or vaginal), pharyngeal and/or rectal sites using the APTIMA Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens for APTIMA/TIGRIS assay.

Patient Preparation:

See collection procedures below.

Supplies:

1. GC/ Chlamydia Gen-Probe supplies See Page III-1 to order.
2. Unisex Collection Kit. Use blue swab only for collecting both male and female specimens.
3. DHEC form 1332

Collection Procedure for Endocervical Swab Specimens:

1. The clinician collects the specimen from the cervical and endocervical area using the APTIMA Unisex Swab (green printing) designed to collect endocervical and urethral specimens for APTIMA/TIGRIS assay. **Please use the blue shaft swab for collection.**
2. Remove excess mucus from cervical os and surrounding mucosa using cleaning swab (white shaft in package with red printing). **Discard this swab!!!**
3. Insert specimen collection swab (blue shaft) into endocervical canal.
4. Gently rotate swab clockwise for 10 to 30 seconds in endocervical canal to ensure adequate sampling.
5. Withdraw swab carefully; avoid any contract with vaginal mucosa.
6. Remove foil cap from swab specimen transport tube and immediately place specimen collection swab into the transport tube.
7. Break off the swab at the scoreline. Use care to avoid splashing contents.
8. Re-cap swab specimen transport tube tightly.
9. Place a label with patient name, date taken, and anatomic site (cervical, Cx) on the tube.
10. Complete a laboratory test requisition for each specimen with the test(s) requested and the appropriate anatomic site (cervical, Cx) indicated on the form.
11. Specimen can be stored in the refrigerator (2-8 degrees C) or room temperature (9 to 30 degrees C) prior to transport to the Public Health Laboratory, 8231 Parklane Road, Columbia, SC 29223.
12. Specimens need to be stored in an upright position in a rack so that the buffer is in contact with the swab.
13. The specimen is good for 60 days.
14. If longer storage is needed, freeze at -20 to -70 degrees C for up to 12 months after collection.

Collection Procedure for Vaginal:

1. The clinician collects the specimen from the vaginal area using the APTIMA Vaginal Unisex Swab (orange printing) designed to collect vaginal specimens for APTIMA/TIGRIS assay. **Please use the pink shaft swab for collection.**
2. Carefully insert the swab into vagina about 2 inches inside the opening of the vagina and gently rotate swab 10-30 seconds.
3. Make sure the swab touches the walls of the vagina so that the moisture is absorbed by the swab and then withdraw the swab without touching the skin.
4. Remove foil cap from swab specimen transport tube and immediately place specimen collection swab into the transport tube.
5. Break off the swab at the scoreline.
6. Tightly screw the cap onto the tube.
7. Place a label with patient name, date taken, and anatomic site (vaginal, vag) on the tube.
8. Complete a laboratory test requisition for each specimen with the test(s) requested and the appropriate anatomic site (vaginal, vag) indicated on the form.
9. Specimen can be stored in the refrigerator (2-8 degrees C) or room temperature (9 to 30 degrees C) prior to transport to the Public Health Laboratory, 8231 Parklane Road, Columbia, SC 29223.
10. Specimens need to be stored in an upright position in a rack so that the buffer is in contact with the swab.
11. The specimen is good for 60 days.
12. If longer storage is needed, freeze at -20 to -70 degrees C for up to 12 months after collection.

The Aptima Vaginal Swab Specimen Collection Kit (pink shaft swab) should only be used for collection of females ≥ 14 years old an non-pregnant.

Collection Procedure for Male Urethral:

Patient should not have urinated for at least 1 hour prior to collection.

1. The clinician collects the specimen from the urethral area using the APTIMA Unisex Swab (green printing) designed to collect endocervical and urethral specimens for APTIMA/TIGRIS assay. **Please use the blue shaft swab for collection.**
2. Insert the specimen collection swab (blue shaft swab in the package with the green printing) 2 to 4 cm into the urethra.
3. Gently rotate the swab clockwise for 2 to 3seconds in the urethra to ensure adequate sampling.
4. Withdraw the swab carefully.
5. Remove foil cap from swab specimen transport tube and immediately place specimen collection swab into the transport tube.
6. Carefully break off the swab at the scoreline. Use care to avoid splashing contents.
7. Re-cap the swab specimen transport tightly.
8. Place a label with patient name, date taken, and anatomic site (male urethral) on the tube.
9. Complete a laboratory test requisition (DHEC 1332) for each specimen with the test(s) requested and the appropriate anatomic site (male urethral) indicated on the form.
10. Specimen can be stored in the refrigerator (2-8 degrees C) or room temperature (9 to 30 degrees C) prior to transport to the Public Health Laboratory, 8231 Parklane Road, Columbia, SC 29223.
11. Specimens need to be stored in an upright position in a rack so that the buffer is in contact with the swab.
12. The specimen is good for 60 days.
13. If longer storage is needed, freeze at -20 to -70 degrees C for up to 12 months after collection.

Collection Procedure for Pharyngeal: *Since this collection kit is designed to collect endocervical specimens, included is a white shaft "cleaning" swab which is NOT to be used for pharyngeal or rectal specimen collection.*

1. The clinician collects the specimen from the pharyngeal area using the APTIMA Unisex Swab (green printing) designed to collect endocervical and urethral specimens for APTIMA/TIGRIS assay. **Please use the blue shaft swab for collection.**
2. Swab area between the tonsillar pillars and the region posterior to the pillars.
3. Remove foil cap from swab specimen transport tube and immediately place specimen collection swab into the transport tube.
4. Break off the swab at the scoreline.
5. Place a label with patient name, date taken, and anatomic site (throat) on the tube.
6. Complete a laboratory test requisition for each specimen with the test(s) requested and the appropriate anatomic site (throat) indicated on the DHEC Form 1332.
7. Specimen can be stored in the refrigerator (2-8 degrees C) or room temperature (9 to 30 degrees C) prior to transport to the Public Health Laboratory, 8231 Parklane Road, Columbia, SC 29223.
8. Specimens need to be stored in an upright position in a rack so that the buffer is in contact with the swab.
9. The specimen is good for 60 days.

Collection Procedure for Male/Female Rectal: *Since this collection kit is designed to collect endocervical specimens, included is a white shaft "cleaning" swab which is NOT to be used for pharyngeal or rectal specimen collection.*

1. The clinician collects the specimen from the rectal area using the APTIMA Unisex Swab (green printing) designed to collect endocervical and urethral specimens for APTIMA/TIGRIS assay. **Please use the blue shaft swab for collection.**
2. **Asymptomatic and/or Symptomatic Males/Females:** moisten swab with sterile saline/tap water and insert into anus and rectum approximately 2-5 cm (1 to 2 inches) and rotate 3-8 times. **NOTE: it is ok to have some fecal contamination that appears as a brown discoloration but NO frank fecal material.**
3. Remove foil cap from swab specimen transport tube and immediately place specimen collection swab into the transport tube.
4. Break off the swab at the scoreline.
5. Place a label with patient name, date taken, and anatomic site (rectal, rec) on the tube.
6. Complete a laboratory test requisition for each specimen with the test(s) requested and the appropriate anatomic site (rectal, rec) indicated on the form.
7. Specimen can be stored in the refrigerator (2-8 degrees C) or room temperature (9 to 30 degrees C) prior to transport to the Public Health Laboratory, 8231 Parklane Road, Columbia, SC 29223.
8. Specimens need to be stored in an upright position in a rack so that the buffer is in contact with the swab.
9. The specimen is good for 60 days.

Collection for Male and Female Urine Specimens

Patient should not have urinated for at lease 1 hour prior to specimen collection.

1. Direct patient to provide first-catch urine (approximately 20 to 30 ml of initial urine stream) into urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. Female patients should not cleanse labial area prior to providing specimen.

2. Remove cap from urine specimen transport tube and transfer 2 ml of urine into urine specimen transport tube using disposable pipette provided. The correct volume of urine has been added when fluid level is between black fill lines on urine specimen transport tube label.
3. Re-cap urine specimen transport tube tightly. This is now known as the "processed urine specimen."
4. See *Specimen Transport and Storage* below.

Specimen Handling:

Complete DHEC form 1332 to accompany specimen
See instructions on back for completing.
Be sure to complete test specific information**.**

Specimen Preservation and Transport

A. Swab

1. After Collection, transport and store swab in swab specimen transport tube at 2°C to 30°C until tested.
2. Specimens must be assayed with the GEN-PROBE APTIMA Combo 2 Assay within 60 days of collection. If longer storage is needed, freeze at -20°C to -70°C for up to 12 months after collection.

B. Urine

1. After collection, transport the processed urine specimens in the GEN-PROBE APTIMA Combo 2 Assay urine specimen transport tube at 2°C or 30°C and store at 2°C or 30°C until tested. Processed urine specimens should be assayed with the APTIMA Assay within 30 days of collection. If longer storage is needed, freeze at -20°C -or-70°C for up to 90 days after collection.
2. Urine samples that are still in primary collection container must be transported to lab at 2°C or 30°C. Transfer urine sample into APTIMA Assay urine specimen transport tube within 24 hours of collection. Store at 2°C or 30°C and test within 30 days.
3. See Section IV for appropriate shipping container, packaging and transport instructions.

Specimen Rejection:

1. No swab in tube, 2 swabs in tube, or improper (non-blue) swab used.
2. Universal rejections, See Section I, *SCDHEC, Public Health Laboratory Services Guide*.
3. Note: specimens collected with this system cannot be used for culture.

References:

1. Probetec Swab Specimen Collection and Handling by Campbell, D., SFDPH Micro Lab and Engelman, J., M.D., City Clinic, 1/2002.
2. APTIMA Swab Specimen Collection Guide; Gen-Probe Incorporated, San Diego, CA 92121.
3. City and County of San Francisco, Dept. of Public Health, City Clinic Branch Laboratory, revised 10/09.

SKIN SCRAPINGS FOR SCABIES

Principle:

Diagnosis of scabies can be confirmed by demonstration of the mites, eggs or scybala (fecal pellets). Because the mites are located under the surface of the skin, scrapings must be taken from the infected area.

Supplies:

1. Mineral oil
2. Sterile scapel blade
3. Clean glass slide and coverslip
4. Applicator stick
5. DHEC form1335
6. Cardboard slide mailer (holds 2 slides)
7. Biohazard bag

Safety Precautions:

Specimens must be handled with care**. *Sarcoptes scabei* is highly contagious. Wear gloves and lab coat while collecting specimens.**

Collection Procedure:

1. Place a drop of mineral oil on a sterile scalpel blade. (Mineral oil is preferred over potassium hydroxide solution or water. Mites will adhere to the oil and oil will not dissolve fecal pellets).
2. Allow some of the oil to flow onto the papule.
3. Scrape vigorously six or seven times to remove the top of the papule. (There will be tiny flecks of blood in the oil).
4. Transfer the oil and scraped material to a glass slide. (An applicator stick can be used).
5. Add **one or two drops** (no more than 2) of mineral oil to the slide and stir the mixture.
6. Place a cover slip on the slide.

Specimen Handling:

1. Place a patient identification label on the edge of the glass slide
2. Complete DHEC form 1335 to accompany specimen. See instructions on back for completing.

Specimen Preservation and Transport:

1. Place slide(s) in cardboard slide mailer. or plastic slide box (not supplied)
2. Secure mailer with rubber band and place mailer in Biohazard bag.
3. Store and ship at room temperature
4. See Section IV for appropriate shipping container, packaging and transport instructions.

Specimen Rejection:

1. Too much oil used (more than 2)
2. Universal rejections, See Section I

Transporting and Shipping Infectious Substances

(Updated January 2019)

Introduction

Patient specimens from most of the SC Health Departments and many of the SC hospitals are transported to the SC DHEC Public Health Laboratory through a DHEC contracted courier system. This courier system picks up and delivers courier mail to over 60 DHEC health departments and locations throughout the state every evening.

For the protection of employees and the public, patient specimens and infectious substances must be properly packaged and labeled. As packages delivered using this courier system are transported in commerce, they must be packaged to meet all DOT requirements for shipping infectious substances. Failure to follow these regulations can result in injury, exposure, and/or fines.

Regulatory Requirements

There are three regulatory entities regarding the shipping of hazardous materials; the International Air Transporters Association (IATA), the United States Department of Transportation (USDOT), and the United States Postal Service (USPS). According to regulations, it is the **shipper's responsibility** to properly package shipments of infectious substances and hazardous materials.

The International Air Transporters Association (IATA) is a private organization whose regulations only apply to air transport by IATA member airlines. All major airlines are members of IATA and follow the IATA *Dangerous Goods Regulations* taken from the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air.

The United States Department of Transportation (US DOT) is a government agency that regulates commercial transport. Commercial transport takes place when money is exchanged for a good or service. All modes of transportation, ground, air, and water, fall under DOT regulations. US DOT regulations are located in the Code of Federal Regulations 49 CFR 173. Updates to these regulations require congressional approval and are not frequently updated.

The United States Postal Service (USPS), has their own regulations found in the domestic mail manual. As one federal agency cannot regulate another federal agency, the USPS is not required to follow US DOT regulations. As an example, the Postal Service can transport cylindrical shippers while a private courier, like Fedex, cannot.

In addition to these regulations, private couriers can have additional regulations. As an example, Federal Express requires that a shippers declaration for Dangerous Goods be typed and not hand written.

The US Department of Transportation (DOT) and the US Postal Service (USPS) harmonized their regulations with the International Air Transporter Association (IATA) regulations in 2006. Therefore, if infectious substance is packaged and labeled to meet the IATA regulations, the package will meet or exceed the requirements for US DOT and the US Postal Service. In addition to providing uniformity, this harmonization allowed the regulations to be more adaptive. As IATA is a private organization, it has the ability to change its regulations without congressional approval.

Training Requirements

All employees who are a part of any step of classifying, packaging, labeling, marking, completing the paperwork, or transporting the specimen must be properly trained to package and ship infectious substances. Training records must be retained for a minimum of thirty-six months. Retraining must be completed every two years from the date of completion for IATA regulations and every three years for DOT regulations.

The training must include:

- An overview of the regulatory requirements
- Security awareness training
- Function specific training on the activities the employee will be responsible for, such as classification of infectious substances, packaging, labeling the outside container and completing shipping documentation.
- Safety training to include understanding the hazards of the infectious agent, safe handling and emergency response procedures.

The employer must certify the employees training as adequate and maintain a record of training which includes:

- The individual's name
- The most recent training completion date
- A description, copy or reference to training materials used
- The name and address of the organization providing the training
- A test, which was completed satisfactorily, to verify the employee understood the training.

Exemptions

Exempted Materials

The following items are exempt from the shipping regulations for infectious substances, but must be packaged to avoid leaking during shipping and may require a special label.

- Specimens in which any pathogens have been neutralized or inactivated
- Specimens/samples **known** to not contain infectious substances
- Specimens/samples which only contain micro-organisms which are non- pathogenic for humans and animals
- Dried blood spots and fecal occult blood samples
- Environmental samples (food and water) that are not considered to pose a significant health risk
- Organs for transplant and blood for transfusion

Private Courier Exemptions

An exemption called the "materials of trade exemption," located at 49 CFR 173.6, is commonly used by hospital and DHEC employees. This exemption has multiple parts, but the part most useful for the transport of infectious substances is the following: "a hazardous material transported on a motor vehicle, by a private carrier in direct support of a principle means of business that is other than transportation by motor vehicle." This exemption does not apply to all hazard classes and there are quantity limits to those materials that are allowed. For infectious substances, this exemption only applies to category B samples.

So, a hospital courier or DHEC employee that transports samples to the health department, can use this exemption, because their principle business is not the transportation of samples but the care and treatment of patients or the community. So, these regulations do not apply to the transport of category B infectious substances transported by a hospital courier or DHEC employee transporting samples to a health department.

In order to protect the safety of the employee and the public, DHEC employees must follow all of the regulations for proper shipping described in further pages. Additionally, secure the package in the vehicle as far away as possible from the driver as possible, preferably in the trunk if available. If there is an accident, emergency responders need to know that infectious substances are in the package.

Definitions:

BIOLOGICAL PRODUCTS: Are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines.

CARBON DIOXIDE, SOLID (DRY ICE): Carbon dioxide, solid (dry ice) is produced by expanding liquid carbon dioxide to vapor and "snow" in presses that compact the product into blocks. It is used primarily for cooling and due to its very low temperature (about -79 C) can cause server burns to skin upon direct contact. When Carbon dioxide, solid (dry ice) converts (sublimates) directly to gaseous carbon dioxide it takes in heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing Carbon dioxide, solid (dry ice) must be designed and constructed so as to prevent build-up of pressure due to the release of carbon dioxide gas.

CONSIGNEE: Any person, organization or government which is entitled to take delivery of a consignment.

CULTURES: Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens as defined in 3.6.2.1.4.

DANGEROUS GOODS: Articles or substances which are capable of posing a risk to health, safety, property or the environment and which are shown in the list of dangerous goods in these Regulations or which are classified according to the Regulations.

EXCEPTION: A provision in these Regulations which excludes a specific item of dangerous goods from the requirements normally applicable to that item.

EXEMPTION: Authorization issued by an appropriate national authority of all States concerned providing relief from the provisions of these Regulations.

INFECTIOUS SUBSTANCES: are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

INNER RECEPTACLE: Are receptacles which require an outer packaging in order to perform their containment function.

OVERPACK: An enclosure used by a single shipper to contain one or more packages and to form one handling unit for convenience of handling and stowage. Dangerous goods packages contained in the overpack must be properly packed, marked, labeled and in proper condition as required by these Regulations. For cooling purposes, an overpack may contain Carbon dioxide, solid (dry ice), provided that the overpack meets the requirements of Packing Instruction 954. (A Unit Load Device is not included in this definition.)

PACKAGE: (Non-Radioactive Material). The complete product of the packing operation consisting of the packaging and contents prepared for transport.

PACKAGING: (Non-Radioactive Material). Receptacles and any other components or materials necessary for the receptacle to perform its containment function and to ensure compliance with the minimum packing requirements of these Regulations.

PACKING: The art and operation by which articles or substances are enveloped in wrappings and/or enclosed in packaging or otherwise secured.

PATIENT SPECIMENS are those collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

PROPER SHIPPING NAME: The name to be used to describe a particular article or substance in all shipping documents and notifications and, where appropriate, on packaging.

RECEPTACLE: A containment vessel, including closures, for receiving and holding substances or articles.

SELECT AGENT: microorganisms or toxins, identified by a panel of experts, which could be used for bioterrorism. A complete list of select agents and toxins may be found on the Select Agent Program's web page http://www.cdc.gov/od/sap/docs/salist.pdf

SHIPMENT: The specific movement of a consignment from origin to destination.

UN NUMBER: The four digit number assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods to identify a substance or a particular group of substances. (The prefix "UN" must always be used in conjunction with these numbers.)

Classifying Infectious Substances

Infectious substances are divided into 2 categories – A and B.

Category A: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.

Indicative examples of substances that meet these criteria are given in Table 3.6.D from the IATA Dangerous Goods Regulation (see next page). This table is not exhaustive. New or emerging pathogens, which do not appear in the table but which meet the same criteria must be assigned to category A.

Organisms listed with the words "cultures only" indicate that clinical specimens of known to contain that organism can be shipped as category B. As an example, Ebola is not listed with "cultures only." Therefore specimens known to contain Ebola must be shipped as Category A.

Other Examples of Category A infectious substances:

- Known culture of a Select Agent
- Known culture of *Escherichia coli* (toxigenic)
- Known culture of *Neisseria meningitidis*
- Known culture of *Mycobacterium tuberculosi*s
- Samples or cultures suspected to be Select Agents or BSL-3 organisms. (As an additional precaution and requested by the PHL)

Category B: An infectious substance which does not meet the criteria for inclusion in Category A.

Examples of Category B infectious substances:

- Most cultures and patient specimens shipped to the Public Health Laboratory
- A swab placed in a genprobe bottle (would not meet the IATA definition of a culture)

Table 3.6.D from IATA Dangerous Goods Regulations
Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicted (No changes from 2018)

UN Number and Proper Shipping Name	**Micro-organism** [NOTE: "Select Agents or Toxins" are shown in red font]
UN 2814 Infectious substance affecting humans	*Bacillus anthracis* (cultures only) *Brucella abortus* (cultures only) *Brucella melitensis* (cultures only) *Brucella suis* (cultures only) *Burkholderia mallei* - *Pseudomonas mallei* - Glanders (cultures only) *Burkholderia pseudomallei* - *Pseudomonas pseudomallei* (cultures only) *Chlamydia psittaci* - avian strains (cultures only) *Clostridium botulinum* (cultures only) *Coccidioides immitis* (cultures only) *Coxiella burnetii* (cultures only) Crimean-Congo hemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) Escherichia coli, verotoxigenic (cultures only) Ebola virus Flexal virus *Francisella tularensis* (cultures only) Guanarito virus Hantaan virus Hantavirus causing hemorrhagic fever with renal syndrome Hendra virus Hepatitis B virus (cultures only) Human immunodeficiency virus (cultures only) Highly pathogenic avian influenza virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus *Mycobacterium tuberculosi*s (cultures only) Nipah virus Omsk hemorrhagic fever virus Poliovirus (cultures only) Rabies virus (cultures only) *Rickettsia prowazekii* (cultures only) *Rickettsia rickettsii* (cultures only) Rift Valley fever virus (cultures only) Russian spring-summer encephalitis virus (cultures only) Sabia virus *Shigella dysenteriae* type 1 (cultures only) Tick-borne encephalitis virus (cultures only) Variola virus Venezuelan equine encephalitis virus (cultures only) West Nile virus (cultures only) Yellow fever virus (cultures only) *Yersinia pestis* (cultures only)

Examples of Classifying Infectious Substances

Material	Infectious Substance, category A	Infectious Substance, category B
Culture of *Mycobacterium tuberculosi*s	**X**	
Sputum from a person infected with *Mycobacterium tuberculosi*s		**X**
Known culture of *Salmonella spp.*		**X**
Known culture of *Bacillus anthracis*	**X**	
Suspected culture of *Bacillus anthracis*	Safer Choice	Technically Correct
Tube of blood from a person known to be infected with *Bacillus anthracis*	Safer Choice	Technically Correct
Tube of blood drawn from patient infected with Ebola virus	**X**	
Animal head shipped for rabies testing		**X**

Proper Shipping Names and UN Numbers

Once the proper category is determined, use the corresponding UN number and proper shipping name for your package. Both of these items are required on the outer packaging and are used in later steps. The proper shipping name must be spelled exactly as seen here.

Classification	Proper shipping name	UN number
Infectious substance, Category A	"Infectious substance, affecting humans" (technical name)	UN 2814
Infectious substance, Category B	"Biological substance, Category B"	UN 3373

For category A, notice the parenthesis at the end. In these parentheses, a technical name must be entered. Abbreviations and non-standard formatting are not allowed. So, no italics for scientific names. Examples could include; Escherichia coli and Neisseria meningitidis.

If you are shipping a sample suspected, but not confirmed, to be a category A infectious substance, and have elected to ship the material as a category A as an additional safety measure, the packing name must use the text "Infectious Substance, Affecting Humans (suspected category A infectious substance)."

Packing Selection and Requirements

Package Construction

Not all packages are acceptable for shipping infectious substances. Packages must follow strict DOT and IATA regulations regarding their size, shape, construction materials, and markings. Approved packaging configurations and requirements are defined by the DOT in 49 CFR 172 and 173, and by IATA in the dangerous goods regulations, section 5, packaging instructions 620 and 650.

Package Performance Testing

Additionally, packages must follow strict manufacturing standards and performance. Performance tests simulate the potential conditions the package may encounter during transit and test the package's ability to contain the hazardous material while enduring stresses like drops, leaks, pressurized atmospheres, and stacking loads. Standards for specific performance tests are located in 49 CFR 178 for the DOT and in the Dangerous Goods Regulations, Section 6 for IATA. Performance tests must be documented and the records must be made available to inspectors upon request.

Packaging Options

Performance packaging accepted by the DHEC contracted courier system, also known as a shipper, falls into three general categories: UN certified shippers, PHL approved shippers, Sender verified packaging. When using a UN certified or PHL approved shipper, you must follow the manufacturer's instructions for closing the package. If the closure instructions specify an order to close the flaps of the box, that order must be followed. Failure to follow the manufacture's closure instructions can result in a DOT fine. It is important to retain a copy of these instructions both for reference as needed and if requested by a DOT inspector. Do not mix and match parts of packages. The package has been certified as a unit. Mixing and matching parts invalidates the UN certification.

1. **UN certified shippers** have been tested by the manufacturer and certified to meet all performance requirements for IATA and DOT. This certification mark (seen right) indicates that the package is UN certified. A UN certified shipper is certified for both Category A and B infectious substances. UN certified shippers, also meet all of the requirements for air transportation, and are universally accepted by national commercial carriers like FedEx or UPS.

INFECON 5000 or 5500

- UN Certified for Category A or B
- Acceptable for aircraft
- Insulated shipper – use for samples needing cold packs or dry ice
- Could be used for samples shipped at room temperature

INFECON 2000 or 3000

- UN Certified for Category A or B
- Acceptable for aircraft
- Only use for samples shipped at room temperature

2. **PHL approved shippers**, indicated by the mark to the right, are shippers provided by the PHL, for which the PHL has conducted performance testing. However, the Public Health Laboratory has only conducted the testing needed for ground transportation of Category B infectious substances. Do not use them for Category A shipments and do not offer this package to a national commercial carrier like FedEx or UPS as it has not met all the requirements for air transportation.

ThermoSafe or Uline Shippers

- Laboratory "Approved"
- Category B only
- Not acceptable for FedEx or UPS (pressure tested for aircraft)
- Insulated shipper – use for samples needing cold packs or dry ice
- Could be used for samples shipped at room temperature

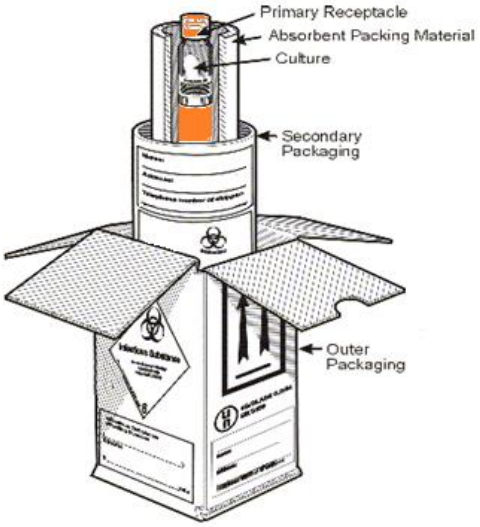
3. **Sender Verified Packaging** may be used if the shipper meets all DOT / IATA regulations and/or has been performance tested by your entity or by the manufacturer. If this option is selected, your entity will be responsible for providing USDOT inspectors with performance test results and/or a statement from the manufacturer.

Triple Packaging

The safe transport of infectious substances is based on "triple-packing." As an example, a primary sample container, in a secondary container, in an outer shipper, offering three layers of protection.

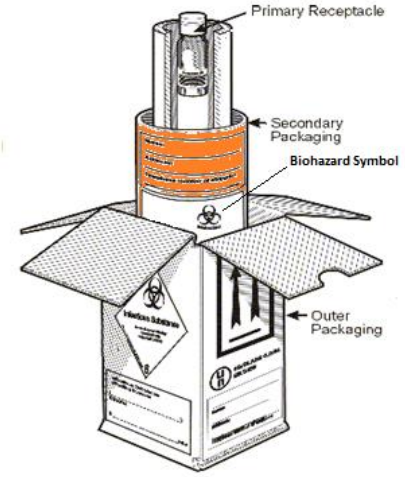
Primary Receptacle

- Is the container (e.g., tube vial, bottle) that holds the specimen.
- Must be securely sealed and leak proof (screw top tubes must have a piece of waterproof tape around the top to prevent the top from coming loose in transit).
- Must be surrounded by absorbent material capable of taking up the entire liquid contents.
- Must be packed in the secondary receptacle in such a way that it will not break.



Secondary Packaging

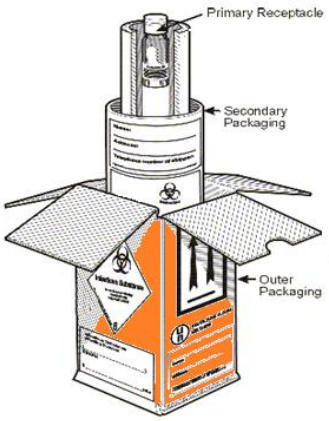
- Is the receptacle into which a primary receptacle and the absorbent and cushioning material are placed.
- Must be leak proof and securely sealed.
- Must be placed in the outer packaging so that it does not move.
- Must have a biohazard symbol.
- Never put dry ice inside a secondary container. The container may rupture because of trapped gasses.
- Never put paperwork inside the secondary container.



Note: For PHL approved containers, a ziplock biohazard bag may serve as the secondary receptacle for a patient specimen if transport is by ground with the DHEC courier system.

Outer Packaging

- Is the receptacle into which the secondary receptacle, along with cushioning materials, is placed.
- Must be rigid.
- Bears all required markings and labels.
- At least one surface of the outer packaging must have a minimum dimension of 4 inches x 4 inches.
- Itemized list of contents, requisition forms, and other paperwork is placed here next to the secondary container.



- Dry ice and cool pack are placed here next to the secondary container.
- Seal the package with clear shipping tape. Do NOT use excessive tape to close the outside container.
- Use caution when opening outer packages. Cut the tape instead of pulling the tape to open the package. Pulling the tape can rip or tear reusable package. Also be careful not to cut the box, specifically cardboard closing tabs.

Over Packaging

- Is not required for all packages.
- Is a larger box containing one or more smaller completely packaged and labeled shippers.
- Must bear all the same marks and labels required by the contents of the shippers it contains.
- Must bear label with the word "Over pack."
- Over packs may be needed if more, surface area is needed on a shipper to accommodate the required marks and labels.

Quantity Limits

For Category B infectious substances, regulations allow:

- Up to 1 liter per primary receptacle
- Up to 4 liters per outer packaging.

For Category A infectious substances, regulations allow:

- Up to 50ml or 50g per shipper on a passenger aircraft.
- Up to 4 liters per shipper on a cargo aircraft.

NOTE: Remember, there must always be adequate absorbent materials next to the primary receptacle to contain all liquid contents should the container leak. The PHL provided absorbent pads are rated to absorb 50ml.

Shipping with Cold Packs or Dry Ice

Check the test section in the *Public Health Laboratory Services Guide,* if unsure of temperature requirements for the infectious substance being shipped.

- If the specimen must be shipped cold, but not frozen, use cold packs around the **outside** of the secondary packaging in an insulated shipper. Do not use ice because it will melt and leak during shipping.

- If the specimen must be shipped frozen, place dry ice around the **outside** of the secondary packaging in an insulated shipper. Never place dry ice inside the secondary container. The same properties that make it leak-proof also make it gas-tight. The container can explode as pressure builds. Additional labeling is required for dry ice. A good rule of thumb is to add at least 6 pounds per 24-hour period.

Shipping Paperwork

The following papers must accompany each package containing infectious substances:

- Itemized list of contents
- Paperwork related to sample testing (requisition forms, results, etc.)
- Declaration of Dangerous Goods (for shipments of Category A or dry ice)

Itemized list of Contents

All packages must be accompanied by an itemized list of contents. This document contains:

- To and From Address
- An Emergency Contact Name and Telephone
- The kind of specimens with a brief description
- The number and total volume of the samples
- The proper shipping classification for the hazards

Itemized List Used by the Public Health Laboratory

Shipped from: SC DHEC Public Health Laboratory
8231 Parklane Road
Columbia, SC 29223
Emergency Contacts: Andrea Causey
Emergency Telephone: (803) 767-8110

Shipped to: _____

_____

_____

Shipping Temperature
_____ ambient
_____ cold packs
_____ dry ice

Next day delivery required
____No
____Yes

Specimen or Culture Examples – culture slant of Salmonella	**Number of tubes or plates**	**Volume in each tube or plate**	**Total volume**	**Proper shipping classification (circle only one)**
				Infectious substance, category A **or** Infectious substance, category B
				Infectious substance, category A **or** Infectious substance, category B

Shippers Declaration for Dangerous Goods

- Required for packages containing a Category A infectious substance and/or dry ice.
- This is a legal document that declares to the courier the hazardous contents in the package.
- A pdf fillable version of this document is available at www.iata.org/whatwedo /cargo/dgr/Documents/Shippers-Declaration-Open-Format-Fillable.pdf
- Small amounts (≤ 30ml) of sample preservative which are classified as Class 3 (flammable) and/or Class 8 (corrosive) materials are not required to be listed on the declaration.
- Use the proper shipping name and UN number as determined in previous steps.
- The document must be attached to the outside (usually the top) of the package in a document pouch. The entire pouch must fit flat on one side of the package.
- The document must be completed in **triplicate**, each as an original, with the red stripe down each side of the paper. Two copies are given to the transporter and one copy is kept for your files.
- These documents must be kept by the sender for a minimum of two years from the date of the shipment.

NOTE - Federal Express does not accept hand written Shipper's Declarations. Refer to www.fedex.com/us for details regarding acceptable electronic methods to prepare this form.

Marks and Labels

The following marks and labels must be present, complete, and unobstructed for proper shipping. Any marks or labels which are defaced, altered, or covered up in any way are invalid.

Secondary Packaging

- Address of the sender
  (with emergency contact information)

From:
DHEC County Health Department
123 Wellness Drive
Health Springs, SC XXXXX
Emergency Contact: Al Ready 803-123-4567

- Biohazard Symbol

(not required if the symbols is present on the secondary container)

Outside Packaging

- Address of the sender
  (with emergency contact information)

From:
DHEC County Health Department
123 Wellness Drive
Health Springs, SC XXXXX
Emergency Contact: Al Ready 803-123-4567

- Address of the intended recipient
  a. Mark the intended laboratory

Ship To:
SC DHEC Public Health Laboratory
___ Clinical Microbiology ___ TB
___ Special Pathogens ___ Virology
8231 Parklane Road
Columbia, SC 29223

- Class 6.2 Hazard Diamond

or

Category B Category A

- UN number and proper shipping name(s)
  - Must be within 6 inches of the 6.2 hazard diamond and on the same side of the box

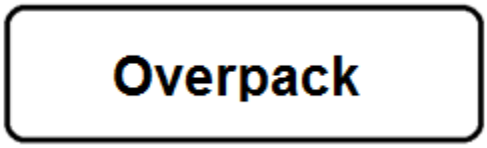
Category A	"UN 2814 Infectious Substance, Affecting Humans" (technical name)
Category B	"UN 3373 Biological Substance, Category B"
Dry Ice	"UN 1845 Dry Ice"

<u>Outside Packaging</u> (Situational)

- If Dry Ice was used,
  - A class 9 hazard diamond
  - Must be within 6 inches of the 6.2 hazard diamond and on the same side of the box
  - Mark the weight of dry ice, in kilograms. One pound = 2.2 kg

and

- "Overpack"
  (if an overpack was used)



- Orientation Arrows
  (if the specimen is liquid)

<u>Emergency Contact Information</u>

- The outside packaging and the secondary container must be marked with an emergency contact name and telephone number for a point of contact of the sender.
- This person must be knowledgeable about the contents of the shipment and be able to provide guidance to first responders who call in case of a spill.
- This number must be immediately answered by the knowledgeable person. An answering service or voicemail is not acceptable.
- An outside contractor that provides this type of service may be used if you have an agreement in place.

Special Situations

Newborn Screening Blood Spots

1. Allow blood spots to **AIR DRY** thoroughly on a level non-absorbent surface such as a plastic coated test tube rack at least 4 hours at room temperature.

2. Place **dried** filter paper form(s) into the provided mailing envelope. Mail the specimen within 24 hours. No additional labeling is required on the outside of the envelope. The dried blood spots cannot leak or spill and are exempt from the dangerous goods/hazardous materials shipping regulations. **The envelopes provided to ship dried blood spots should not be used to ship any other type of patient specimen.**

3. Overnight shipping is recommended. The Public Health Lab (PHL) has a FedEx account to cover the cost of shipping newborn screening specimens to the PHL. To enroll to use this FedEx account, contact PHL at 803-896-0795.

Suspected Bioterrorism Specimens and Cultures

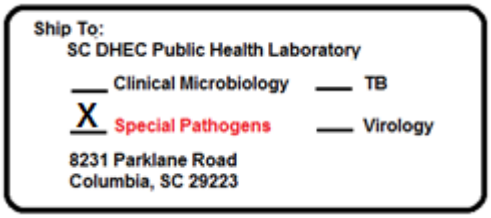
Prior notification is requested for specimens and/or cultures being sent for "rule out/rule in" testing for bioterrorism agents. Please notify: The Special Pathogens Supervisor, **Amanda Moore, 803-896-0777** before shipping these specimens or cultures**.** Alternate: Megan Davis, 803-896-0870

Use only UN certified packaging. UN certified shippers specific to the special pathogens program are available upon request. See the section on Requesting Shipping Supplies.

Classification of the infectious substance is the shipper's responsibility and should be based on the available information. We encourage shipping suspected bioterrorism samples as Category A infectious substances as an additional precaution.

If you are shipping a sample suspected, but not confirmed, to be a category A infectious substance, and have elected to ship the material as a category A as an additional safety measure, the packing name must use the text "Infectious Substance, Affecting Humans (suspected category A infectious substance)."

To ensure that the sample is routed to the correct laboratory. Please verify that the Special Pathogens Laboratory has been marked on the "To" shipping label.



[NOTE] Special Pathogens pre-labeled shippers may be obtained by calling 803-896-0777 / 803-896-0773 (limit 2 per laboratory).

Public Health Laboratory Shipping Address:

Public Health Laboratory
8231 Parklane Road
Columbia, SC 29223

Business hours are 8:00 AM to 4:00 PM
Monday through Friday, except for state holidays

Public Health Laboratory Contact Information:

24/7 telephone number: 803-896-0800

Safety Office: 803-896-0956

Requesting Shipping Supplies: 803-896-0913

Requesting Shipping and Specimen Collection Supplies

Shipping supplies are available without charge to support DHEC programs. Supplies include:

- Shippers (described on page IV-10 and IV-11)
- Mark and Label Stickers (hazard diamonds, UN numbers, etc.)
- Biohazard bags,
- Absorbent materials
- Requisition forms
- Specimen Collection Supplies

To request materials, please contact the PHL supply section at 803-896-0913.

References for Information in This Document:

IATA *Dangerous Goods Regulations*, 60th edition, effective January 1, 2019 to December 31, 2019

Code of Federal Regulations, 49 CFR Parts 171-180, (US Department of Transportation's Hazardous Materials Regulations)

United States Postal Service, *Domestic Mail Manual*

Code of Federal Regulations, 42 CFR Part 73, (Select Agent Regulations)

Centers for Disease Control and Prevention, *Guidelines for the Shipment of Dried Blood Spot Specimens.*

TEST FEE POLICY

The Public Health Laboratory is only partially supported by legislative appropriations from State Funds. Therefore, we have been authorized to charge fees under certain conditions.

TEST FEES:
A fee is charged for those tests which benefit only the individual patient or which are readily available from private sources.

Exempt from charges:

A. Test (s) that is not reasonably available from qualified private laboratories.
B. Test (s) whose result is primarily of epidemiologic or public health significance.
C. Test (s) run as a matter of lab policy which is not requested by the physician.
D. When the patient is medically indigent. In this case, the physician will be billed, but may deduct the charges before remitting. See billing procedures.
E. Repeat tests for Newborn Screening. If the repeat test was requested by the Public Health Laboratory, i.e., initial test was invalid due to early dismissal, or improperly collected specimen or insufficient quantity or other reason, there is no charge for the repeat test. ***All initial and second tests are subject to the full fee*.**

BILLING PROCEDURE

Clients/Customers will be billed monthly by an itemized invoice that includes the patient's name, medical record number, specimen number, date mailed, test(s) performed, and the test fees for each specimen. Billing invoices are generated by Sender and/or Billing numbers. Please note that the Public Health Laboratory **does not** bill Medicaid or any private insurance companies.

Payments:

1. Do not send payment with the specimen. Pay only when you receive a billing invoice. Note: Please do not send cash payments.

2. The billing invoice will consist of two copies: The remittance copy must be returned with your payment for proper crediting of your account. Please retain the provider copy for your records. On the left side of the billing invoice there is a column headed "Eligible for NON payment." Please place an "X" in this column beside the name of any patient listed who is considered to be unable to pay for the test, i.e. indigent. Place the total charges for patients eligible for non-payment in the indicated space at the upper right-hand corner of the billing invoice and deduct this amount from the total charges. Please indicate the amount remitted on the line designated on the billing invoice. Please make check payable to South Carolina Department of Health and Environmental Control (SCDHEC) and remit to the Attention of: Bureau of Financial Management, PO Box 100103, Columbia, South Carolina 29202-3103. If you have any questions pertaining to your account, please notify the Public Health Laboratory immediately at (803) 896-0800.

3. Payment can be accessed on DHEC website at http://www.scdhec.gov. Click on "For Business" then click on "Pay Invoices". **Note: Total payment amount online for debit/credit card payment is limited $3,000.00 with a $1.00 transaction fee. Total payment amount greater than $3,000.00 can be paid online by electronic check.**

PUBLIC HEALTH LABORATORY SERVICES GUIDE
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